Exhibit B

REDACTED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

****

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION — MDL No. 2875

****

THIS DOCUMENT APPLIES TO ALL CASES — HON ROBERT B. KUGLER

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- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

Videotaped Deposition of PUNAM ANAND KELLER, Ph.D., commencing at 9:19 a.m. Eastern, on the 10th of March, 2022, at the offices of Duane Morris, 100 High Street, Boston, Massachusetts, before Maureen O'Connor Pollard, Registered Diplomate Reporter, Realtime Systems Administrator, Certified Shorthand Reporter.

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GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

APPEARANCES:

GOLOMB & HONIK PC
BY: RUBEN HONIK, ESQ.
1835 Market Street, Suite 2900
Philadelphia, Pennsylvania 19102
215-327-9166
ruben@honiklaw.com
Representing the Plaintiffs

SLACK DAVIS SANGER, LLP
BY: JOHN R. DAVIS, ESQ.
BY: BETH QUESTAD, Paralegal (remotely)
6001 Bold Ruler Way, Suite 100
Austin, Texas 78746
512-795-8686
jdavis@slackdavis.com
Representing the Plaintiffs

KANNER & WHITELEY, LLC
BY: CONLEE WHITELEY, ESQ. (Remotely)
701 Camp Street
New Orleans, Louisiana 70130
504-524-5777
c.whiteley@kanner-law.com
Representing the Plaintiffs

DUANE MORRIS, LLP
BY: SETH A. GOLDBERG, ESQ.
BY: ALEKSANDER SMOLIJ, ESQ.
BY: DANA B. KLINGES, ESQ. (Remote)
30 South 17th Street
Philadelphia, Pennsylvania 19103
215-979-1164
sgoldberg@duanemorris.com
dklinges@duanemorris.com
Representing the Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Prinston Pharmaceutical Inc., Huahai U.S., Inc., and Solco Healthcare US, LLC

APPEARANCES (Continued):

DUANE MORRIS LLP
BY: REBECCA BAZAN, ESQ. (Remote)
505 9th Street, N.W., Suite 1000
Washington, DC 20004-2166
202-776-5253
rebazan@duanemorris.com
Representing the Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Prinston Pharmaceutical Inc., Huahai U.S., Inc., and Solco Healthcare US, LLC

CROWELL & MORING LLP
BY: DANIEL T. CAMPBELL, ESQ. (Remote)
1001 Pennsylvania Avenue, NW
Washington, DC 20004
202-624-2774
dcampbell@crowell.com
Representing the Defendant Cardinal Health, Inc.

GREENBERG TRAURIG LLP
BY: TIFFANY M. ANDRAS, ESQ.
77 West Wacker Drive, Suite 3100
Chicago, Illinois 60601
312-456-1065
andrast@gtlaw.com
Representing the Defendants Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals SA, Inc., Actavis LLC, and Actavis Pharma, Inc.

HUSCH BLACKWELL LLP
BY: SARAH ZIMMERMAN, ESQ. (Remote)
190 Carondelet Plaza
St. Louis, Missouri 63105
314-345-6664
sarah.zimmerman@huschblackwell.com
Representing the Defendant Express Scripts, Inc.

APPEARANCES (Continued):

GREENBERG TRAURIG, LLP
BY: DOUGLAS JOHNSON, ESQ. (Remote)
Terminus 200
3333 Piedmont Road NE
Suite 2500
Atlanta, Georgia 30305
678-553-2100
johnsondo@gtlaw.com
Representing the Defendants Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals SA, Inc., Actavis LLC, and Actavis Pharma, Inc.

WALSH PIZZI O'REILLY
BY: CHRISTINE I. GANNON, ESQ. (Remote)
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
973-757-1017
Representing the Defendants Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals SA, Inc., Actavis LLC, and Actavis Pharma, Inc.

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP
BY: FRANK H. STOY, ESQ. (Remote)
One Oxford Centre
Pittsburgh, Pennsylvania 15219
412-263-1840
fhs@pietragallo.com
Representing the Defendant, Mylan Pharmaceuticals, Inc.

APPEARANCES (Continued):

NORTON ROSE FULBRIGHT US LLP
BY: D'LESLI M. DAVIS, ESQ. (Remote)
2200 Ross Avenue, Suite 3600
Dallas, Texas 75201
214-855-8000
dlesli.davis@nortonrosefulbright.com
Representing the Defendant McKesson Corporation

HINSHAW & CULBERTSON, LLP
BY: GEOFFREY M. COAN, ESQ. (Remote)
53 State Street
Boston, Massachusetts 02109
617-213-7047
gcoan@hinshawlaw.com
Representing the Defendant SciGen Pharmaceuticals

BARNES & THORNBURG, LLP
BY: KARA KAPKE, ESQ. (Remote)
11 S. Meridian Street
Indianapolis, Indiana 46204
317-231-6491
kara.kapke@btlaw.com
Representing the Defendants CVS Pharmacy, Inc., and Rite Aid Corporation

FALKENBERG IVES, LLP
BY: MEGAN A. ZMICK, ESQ. (Remote)
230 W. Monroe Street, Suite 2220
Chicago, Illinois 60606
312-566-4808
maz@falkenbergives.com
Representing the Defendant Humana

APPEARANCES (Continued):

BUCHANAN INGERSOLL & ROONEY PC
BY: ASHLEY D.N. JONES, ESQ. (Remote)
1700 K Street, N.W., Suite 300
Washington, DC 20006-3807
202-452-7318
ashley.jones@bipc.com
Representing the Defendant,
Albertsons, LLC

Videographer: Alex Jandrow

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None.

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None.

Questions Marked Highly Confidential
PAGE LINE
None.

P R O C E E D I N G S

THE VIDEOGRAPHER: We are now on the record. My name is Alex Jandrow, I'm a videographer for Golkow Litigation Services.

Today's date is March 10, 2022, and the time is 9:19 a.m.

This video deposition is being held in Duane Morris LLP of Boston Massachusetts in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation, MDL Number 2875, for the United States District Court, District of New Jersey.

The deponent is Punam Keller, MD.

And the court reporter is Maureen O'Connor Pollard.

Counsel will now introduce themselves for the record.

MR. DAVIS: John Davis and Ruben Honik for the plaintiffs.

MR. GOLDBERG: Seth Goldberg on behalf of the ZHP defendants and defendants.

MR. SMOLIJ: Alek Smolij on behalf of the ZHP defendants.

MS. ANDRAS: Tiffany Andras on behalf of Teva and Actavis Pharmaceuticals.

MR. DAVIS: Good morning, Dr. Keller. How are you today?

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PUNAM ANAND KELLER, Ph.D., having been duly identified and sworn, was examined and testified as follows:

///

THE WITNESS: And the first thing I want to do is, it's not MD, it's Ph.D.

EXAMINATION

BY MR. DAVIS:

Q. Okay. Let me try that again.

Good morning, Dr. Keller. How are you this morning?

A. Good. How are you?

Q. Okay. Let me start just with some background questions for you.

When were you engaged as an expert in this case?

A. In -- at the end of last year.

Q. Okay. So November, December?

A. Yes, that period.

Q. Okay. Have you given testimony under oath before?

A. Yes.

Q. Okay. About how many times?

A. Three, including this one.

Q. Okay. So two prior times.

Would that have been in the capacity as an expert witness?

A. Yes.

Q. Your CV, I believe, lists two Johnson & Johnson pelvic mesh cases. Is that what you're referring to for your past testimony?

A. Yes.

Q. Okay. Have you offered an expert report in a case where you have not been deposed under oath?

A. Yes.

Q. About how many times?

A. Three.

Q. Okay. And the -- going back to the J&J pelvic mesh cases, on whose behalf did you submit an expert report?

A. Defendants.

Q. That would be the Johnson & Johnson defendants?

A. Johnson & Johnson/Ethicon.

Q. Which is a subsidiary of Johnson & Johnson?

A. Yes.

Q. To the best of your recollection, what did those expert opinions relate to?

A. They related to my expertise on consumer decision-making.

Q. In the context of evaluating Ethicon/J&J's marketing of their pelvic mesh products?

A. Could you repeat that question?

Q. Sure.

Would that have been in the

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context of J&J and Ethicon's marketing and promotion of their pelvic mesh products?
A. Could you be more specific?
Q. Well, sure.
Why don't you tell me what your -- what you were evaluating from a consumer decision-making standpoint regarding Ethicon's pelvic mesh products.
A. I was providing opinions on how consumers -- the range of consumer responses to Ethicon's marketing communication for the pelvic mesh.
Q. You mentioned Ethicon's marketing communications. Can you describe to me what those included?
A. It's been a while. So to the best of my recollection, it was brochures, and I don't remember anything else.
Q. Okay. Brochures like the product labeling, or handouts to physicians?
A. I don't recall.
Q. Okay. Did you do any kind of empirical study, like a survey, in that case?
A. That was not my -- no, that was

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not my task.
Q. Okay. Have you ever done a damages analysis as an expert in a litigation?
A. Define what you mean by "analysis."
Q. Have you ever been tasked, for example, with calculating the amount of litigation damages in a case?
A. No.
Q. Okay. Have you -- I believe you may have answered this indirectly, but you said you did not do a survey or other empirical study of any kind in the J&J case. Have you ever done a survey or empirical study of any kind in litigation in an expert capacity at all?
A. No.
Q. Okay. Have you ever conducted a survey or some other kind of empirical study outside the context of litigation?
A. Yes, frequently.
Q. Frequently.
Okay. Describe for me, just

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walk me through briefly your educational background, if you don't mind.
A. I have a bachelor's in -- from -- it used to be called Bombay University, because that was the name of the city, it's now been changed to Mumbai, but it was first Bombay University. And I majored in economics and statistics, and -- major in economics, minor in statistics.
And then I got an MBA with a major in marketing also from Bombay. The name of the school also has been changed a little bit, but it used to be called, in short, JBIMS.
And then I came to get a Ph.D in marketing from Northwestern University in the Kellogg school of management.
Q. Thank you.
So your postgraduate degrees, meaning your MBA and Ph.D, those are in the field of marketing?
A. Yes.
Q. Okay.
A. I'd like to just add with, my

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specialization is consumer behavior.
Q. Okay. I've seen that variously referred to as consumer psychology. Similar concept?
A. Yes.
Q. Okay. Did you go straight to academia after obtaining your postgraduate degrees?
A. Yes.
Q. Okay. Walk me through just very briefly that history, if you don't mind, and conclude with what you're doing currently.
A. I -- upon graduation from the Ph.D program, I have held marketing positions in multiple institutions.
Do you need a list of all the institutions?
Q. I don't believe so, but let me clarify.
You said "marketing positions." You mean like faculty?
A. Yes, I was a marketing professor.

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Q. Marketing professors.
Okay. And you're currently a professor of marketing at Dartmouth?
A. At the Tuck School of Business at Dartmouth.
Q. Do you teach undergrad or graduate students there?
A. Both.
Q. Both. Okay.
All marketing classes?
A. All related to marketing.
Q. Okay. My next question was what's your research focus, but I believe you answered that by telling me it's consumer behavior and consumer psychology. Is that how you would describe your research focus?
A. That would be the broadest description. A more specific description would be with an emphasis on how consumers process information, form attitudes and beliefs, intentions to purchase, and purchase products and services. And the two contexts that I study are health and financial well-being.

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MR. DAVIS: Okay. I'm going to mark Keller Exhibit 1, which I'm handing to the reporter.
A. Thank you.
(Whereupon, Keller Exhibit Number 1 was marked for identification.)
BY MR. DAVIS:
Q. Do you recognize that as a web bio for you, Dr. Keller, from the Analysis Group website?
A. I have actually not seen this on the website before, but, okay.
Q. So your testimony is you've never seen this bio for you that's on the Analysis Group website?
A. No, I didn't say that. I know that they sought approval for putting my bio on their website, and they asked me for some information, and my recall is that I approved it. But I didn't actually see it on the website.
Q. Okay. So under -- there's a paragraph under "Summary of Experience"

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there. Did you draft that and provide that to them?
A. I don't recall.
Q. Okay. But you did say you approved the content, I suppose, right?
A. Yes.
Q. Okay. It says that "Professor Keller is an expert in consumer information processing and choice behavior. She studies the application of social marketing principles and behavioral theory in consumer and employee contexts, with a focus on designing and implementing consumer communication programs."
Did I read that correctly?
A. Yes.
Q. Do you agree with that description of your expertise?
A. It's a subset of my expertise, yes.
Q. When you say "a subset," what do you mean by that?
A. I just shared, you know, I have broad expertise that goes beyond how

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consumers process information. It also includes how consumers form attitudes and beliefs, intentions to purchase, and purchase behavior of products and services.
Q. Okay. So this -- you would say that this description that I just read you from your Analysis Group bio would be sort of a subset, as you say, of your broader expertise in the field of consumer behavior?
A. Yes. I view it as a summary. Like any summary bio, it is not going to be exhaustive.
Q. Have you ever taught an economics class, Dr. Keller?
A. No.
Q. Do you have any postgraduate degrees in economics?
A. No.
Q. Do you research in the field of economics?
A. Please be more specific.
Q. Well, does any of your research -- would you characterize any of the research that you've done or publications

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that you've authored, have they been in the field of economics?
A. Yes, in the field of behavioral economics.
Q. Explain what you mean by "behavioral economics."
A. So -- and I'm going to try to simplify things, and just for the purposes of comparison.
By no means do I want to say that what I'm saying is an exhaustive description of both fields because that would take us many, many days.
From my point of view, and many others, economics -- when economists, or in the field of economics, when they study consumers they use utility theory, and the field of behavioral economics was formed because utility theory was inadequate to explain consumer behavior.
To the best of my recollection, there are at least four Nobel Prize winners in the four economic sciences, the Nobel Prize in economic sciences that work on

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behavioral economics.
Q. Okay. But I guess if I'm understanding you correctly, and keeping it high level, when you say "behavioral economics," you're still -- that still falls within the field of consumer behavior, correct?
A. It is, and beyond. So I have co-authors that are behavioral economists that are in the economics department.
Q. But your focus would be on the behavioral aspect of it, correct?
A. In large part, yes.
Q. Okay. Are you on any review boards, editorial boards, or do you have any peer-review duties for any economics-related journal?
A. Yes. And I want to give you an example. The Journal of Consumer Research, for which in the past I was an area editor, which is even higher than an editorial board member, and have been on the editorial board for many years until recently, is made up of multiple subdisciplines such as psychology,

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sociology, economics, and anthropology.
Q. Can you think of any other journals, or is that the one?
A. So Journal of Consumer Psychology is similar. Many of the journals are multidisciplinary, and so it's hard for me to separate the disciplines.
Q. You said that there were multiple subdisciplines, for example, for the Journal of Consumer Research. Was your -- and I think you said you were an area editor?
A. Correct.
Q. Okay. What do you mean by "area editor"?
A. So the review process varies for different journals, but a common review process is when a paper is submitted for review for possible publication in the journal, the editor works with the area editor to determine who those reviewers will be, and after the reviews are -- after the reviews do their peer reviews, the area editor gets all of the reviews and makes a recommendation to the editor for the

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progression of that manuscript for maybe a revision, rejection, acceptance, etcetera.
Q. So by "area editor," is that by -- sort of by discipline? "Area" means sort of discipline, and you would assign out -- you would, as the area editor, say you got a manuscript in, you would review the manuscript and say, Oh, well, this pertains mostly to the psychological subdiscipline, so I'm going to send it over to this particular reviewer? Is that sort of how it works?
A. It's quite close, yes.
Q. Okay.
A. You try to find reviewers who are experts in the subject matter of the article -- sorry, of the paper, not an article yet, so that they can provide an expert opinion.
Q. Okay. So as the area editor, you would not have been doing the peer reviewing yourself, you would have been assigning it out to peer reviewers based on their area of expertise?
A. I write a separate report, and

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that also in that report includes my own review of the article. And it's, I would say, similar to what I would do as a reviewer on the editorial review board.

Q. Okay. Putting aside your behavioral economics, you wouldn't hold yourself out as an expert in economic theory, would you?

A. Please define what you mean by "economic theory."

Q. Well, sure. I mean, would you agree that the field of economics, like there's, for example -- let me strike that.

There's an economics department at Dartmouth, for example, correct?

A. Yes.

Q. Okay. And you said you've never taught an economics class there?

A. Correct.

Q. Okay. Or anywhere, correct?

A. Correct.

Q. Okay. For any of the course subject matter that would be subject to a Ph.D in economics, you wouldn't characterize

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yourself as an expert on any of that, would you?

A. I'm sorry, what do you mean by "any of that"?

Q. Well, any -- let me reframe.

So you had to do quite a bit of work to get your Ph.D in marketing, correct?

A. Yes.

Q. Okay. Would you imagine that there's -- to get a Ph.D in economics, you have to also do quite a bit of work that's different?

A. Yes. And I'm sure there's some overlap as well.

For example, in a Ph.D program, and I was in a Ph.D program in the business school where people were getting their Ph.Ds with different specializations, and we all had to take core classes, so our core classes overlapped. And then we had what you might call elective, so they're not called that in a Ph.D program. So we all had core classes, and then elective classes for our specialization. Yeah.

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Q. Sure. I don't disagree with you that there's some level of crossover, but do you agree that economics is a separate and distinct discipline from marketing?

A. I do not. Marketing is really a combination of multiple disciplines, which is why the premier journal, the Journal of Consumer Research, has in their description of why the journal was formed was to encourage researchers from multiple disciplines, including economics, to study the intersection between consumer research and economics, because we're talking about economics, it's true also for psychology, anthropology, etcetera.

So it is very difficult for me to say that as a consumer researcher that I don't have any knowledge of economics.

Q. I'm not saying that you don't have any knowledge of economics. I'm just asking if you would agree that it's a separate discipline.

A. Is there a separate degree in economics, yes.

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Q. Okay. And, for example, at Dartmouth there's a separate department of economics that has a separate faculty of professors and Ph.Ds who teach economics, correct?

A. Yes. And since the time that I've been at the Tuck School of Business at Dartmouth, three of the faculty members from the department of economics at Dartmouth College in the college of arts and sciences are now faculty members in the Tuck School of Business.

Q. Okay. Faculty members of what exactly?

A. We are all faculty members of management with subspecialties.

Q. Okay. And their subspecialty, for example, would be the economics side of what you would study to get an MBA from Tuck, correct?

A. Yes.

Q. Okay. Do you have any what I would call -- well, are you familiar with the prescription drug approval process in the

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United States?
A. I am not an expert, and don't have an opinion on that.
Q. Okay. You do some health-related messaging initiatives, though, don't you? And you study -- I believe you said one of your consumer behavior sort of sub-research interest was health choices, correct?
A. Yes.
Q. Okay. So does that -- do you have some level of knowledge of how prescription drugs are approved in the US?
A. I am an expert on how consumers make health-related decisions. I am not an expert on the approval process for health products and services.
Q. Okay. Do you know what an NDA is, for example?
A. No.
Q. What about an ANDA?
A. No.
Q. Okay. Do you at least have an understanding that prescription drugs can't

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just simply be sold in the United States, that they actually have to go through a pre-approval process?
A. Yes.
Q. You shrugged a little bit there. Is there some level of confusion or...
A. I shrugged because there were two questions, but I decided to answer because it was approval and pre-approval. And that's okay.
Q. Sure. And if any of my questions are unclear, just ask me for clarification.
A. Thank you.
MR. HONIK: Before you proceed. Maureen, I have an e-mail from someone saying they're waiting to get in. I don't know who is letting people into the Zoom.
THE WITNESS: Clearly I'm not.
THE VIDEOGRAPHER: Do you want to go off the record so I can let them in?

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MR. HONIK: You can stay on. It will just take a second, right? Thank you.
Sorry for the interruption.
(Pause.)
BY MR. DAVIS:
Q. Okay. So just to clarify my last question, you do understand that prescription drugs have to be pre-approved in the US, but I think your testimony is that you don't know much beyond just that fact, is that right?
MR. GOLDBERG: Objection to form.
A. That is not what I said. You asked me the question, and I answered it. And you did not ask me about anything beyond that, because that is vague, I don't know what beyond that means.
BY MR. DAVIS:
Q. Okay. So, well, let me rephrase it.
What you're saying is you're generally familiar with the fact that

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prescription drugs have to be pre-approved in the US, but you are not familiar with the details of how that happens?
A. I am not an expert on the pre-approval or the approval process --
Q. Okay.
A. -- for prescription drugs.
Q. And likewise, is it your testimony that you would not have any expertise in FDA regulations regarding prescription pharmaceuticals after the point of approval?
A. Could you repeat that?
Q. Sure.
Would it likewise be your testimony that you don't have any particular expertise regarding FDA regulations of prescription pharmaceuticals after the point of approval?
A. I don't understand the question.
Q. Sure.
Do you understand that there are FDA regulations of approved prescription

pharmaceuticals?
A. Yes.
Q. Okay. Have you studied them in any detail?
A. You would have to be more specific.
Q. Have you studied those FDA regulations that you just testified existed in any detail?
A. What does it mean "in any detail"?
Q. Have you looked at the -- for example, have you looked at Title 21 of the Code of Federal Regulations?
A. No.
Q. Okay. Have you looked at any FDA regulations regarding prescription pharmaceuticals?
A. You would need to be more specific.
Q. Sure.
You testified you were retained in this case in, I think, November or December of last year you said, correct?

A. Yes.
Q. Since that time, do you recall looking at, as part of your work on this case, any FDA regulations regarding prescription pharmaceuticals?
A. As is outlined in my report, I looked at some FDA-sourced material related to the valsartan recall.
Q. That would be FDA announcements and the like specifically related to valsartan, correct?
A. To the best of my recall, yes.
Q. Okay. Do you recall looking at any FDA regulations of general applicability to prescription pharmaceuticals as part of your work in this case?
A. Not that I recall.
Q. Do you know what cGMPs are?
A. I know what the acronym stands for.
Q. Okay. What is that?
A. Current manufacturing -- sorry, current good manufacturing practices.
Q. Okay. Have you actually looked

at what the FDA regulations are regarding cGMPs?
A. I am not an expert on manufacturing processes. I'm an expert on consumer decision-making.
Q. Okay. Have you reviewed any FDA or congressional definitions of adulteration and misbranding of drugs?
A. First, those were multiple questions. Could you ask, and be specific.
Q. Sure, I'll break it down.
Have you reviewed any FDA or congressional definitions of "adulteration"?
A. No.
Q. Okay. Same question for "misbranding."
A. No.
Q. You don't have any expertise in chemistry, do you?
A. Please define "expertise in chemistry."
Q. Have you studied chemistry ever?
A. Only in school, high school.

Q. Okay. So you would not call yourself an expert chemist?
A. No.
Q. How about toxicology?
A. I would not consider myself an expert in toxicology.
Q. I'm going to mark your report, Dr. Keller, as Exhibit 2.
(Whereupon, Keller Exhibit Number 2 was marked for identification.)
MR. GOLDBERG: She has a copy of it.
A. A copy of my report, yes. It's okay, I'm happy to use yours.
BY MR. DAVIS:
Q. You can keep mine, the marked copy, but if you feel more comfortable reviewing yours, that's fine.
A. No, I'm fine with either copy.
MR. DAVIS: Do you want a copy, Seth?
MR. GOLDBERG: I'll take it just for recordkeeping purposes.

Thank you.
BY MR. DAVIS:
Q. Do you recognize what I've handed to you as your expert report in this case?
A. Yes.
Q. Okay. In drafting that expert report, did you familiarize yourself at all with Federal Rule of Civil Procedure 26 which governs the use of an expert report in federal court litigation?
A. No, I did not do it for this case, but I did in the past when I had to create an expert witness report.
Q. I'm going to read a statement from that rule, and I'm going to ask you if you feel your report complies with that. It says, "The report must contain a complete statement of all opinions the witness will express, and the basis and reasons for them."
Do you feel that your report complies with that provision of Rule 26?
A. Yes.
Q. Okay. Thank you.

So there are no opinions that you would be seeking to offer in this case that are not in your report, is that correct?
A. Yes.
Q. And you've cited everything that -- to the best of your ability, you've cited everything that would support your opinions in that report?
A. No, I cannot cite everything that would support my opinions. This is a subset of citations that would support my opinions.
Q. Sure. Let me reframe the question.
Are there any cites that are out there that you intended to put in your report that didn't make it in, to the best of your memory and knowledge?
MR. GOLDBERG: Objection to form.
A. Yeah, I don't know how to answer the question.
BY MR. DAVIS:
Q. Well, I'm just asking, and

maybe I should rephrase it, is, are there any citations out there to anything that you neglected to put in your report that you want to tell me about today?
A. Well, I did not cite many of my own publications because I felt that my experience and my opinions reflected that research expertise.
Q. Okay. So with the exception of your research in publications, is there any citation that's not in your report that you'd like to tell me about today?
A. No.
Q. Okay. I believe your report is signed January 12, 2022, is that right? I believe that would be on the last page of your report.
A. Yes.
Q. Do you recognize that as your signature?
A. This one isn't signed.
MR. DAVIS: Seth, do you know why that would be?
MR. GOLDBERG: I don't. I

don't know how you would have a not signed copy. That's interesting.
Can I see what you have there?
THE WITNESS: (Handing).
MR. DAVIS: It looks like it's a digital signature. Perhaps it just got -- when it got printed, that got removed from the printing.
A. My copy is signed.
BY MR. DAVIS:
Q. My electronic copy is also signed, so it must be a printing error.
Okay. So looking at --
A. Can I have --
MR. HONIK: Here's one with a signature if you want it.
MR. DAVIS: Should we trade out?
MR. GOLDBERG: Sure. We can do that later.
BY MR. DAVIS:
Q. So when you signed your report on January 12, 2022, did you feel that you had set forth your complete statement of your

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opinions and the basis and reasons for them?
A. Yes.
Q. Okay. You didn't do any kind of survey or empirical study as part of your assignment in this case, did you?
A. No, because I felt that there was evidence from consumers as well as literature from consumers that were sufficient to support my opinions.
Q. We'll get into that a little bit later.
But your answer is no, you did not do a survey or any kind of empirical study as part of your assignment in this case?
A. Yes.
Q. Okay. Have you been asked to at some point in the future?
A. No.
Q. I think you said earlier that you've done some consumer messaging in the field of healthcare, is that correct?
A. Yes.
Q. Okay. Can you describe that

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work generally to me?
A. I use my expertise in consumer decision-making to design communications that would create value for consumers.
Q. And I think -- so is it fair to say that that messaging is directed to consumers specifically?
A. In large part. I have also done work to design health communication to physicians to help them create value for consumers.
Q. What was -- let's start with the messaging to consumers that you described. What would be the substance of those messaging campaigns that you've designed?
A. As I've stated in my report, message factors are part of one of my frameworks, acronym MICI -- that stands for message-individual-contextual factors and the interaction between those -- are very important, so the message part of that is very important for consumers to consider as inputs when they are making a health product

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or service valuation. And the messages contain information on the benefits and the costs of the advocated action to help consumers make the value determination.
Q. Well, let's move away from the theoretical for a moment.
And on the specific sort of messaging that you've designed for healthcare consumers, can you give me some examples of what the substance of those messages conveyed to them were?
A. So first I object to it being characterized as "theoretical," because it is also very practical.
And an example of the message would be, you know, here are the benefits of following -- in the message, there's a portion of the message that would focus on, Here are the benefits of following the advocated recommendations.
Q. Let me --
A. For example --
Q. I didn't mean to cut you off.
A. For example, one of my studies

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is on encouraging women to get a -- to get screened regularly for mammograms, and so, you know, I would list the benefits of getting a mammogram, and then also try to anticipate some of the costs from a consumer point of view and try to overcome those.
So, for example, a potential cost for a consumer might be the discomfort or pain from the mammogram testing procedure, and in my message I might include some coping methods for that, including managing expectations and maybe, you know, asking them to check to see if they can take pain medication and the like.
Q. Okay. So you've given me an example, I believe, of an advocated recommendation, I believe that's the term you used, and that's getting screened for a mammogram. That would be an example of an advocated recommendation --
A. Yes.
Q. -- is that correct?
For mammograms, let's run with that example. For a mammogram, are there any

sort of guidances or anything similar to that about when and how often individuals should get screened?

A. Yes.

Q. Okay. Would some of the content that's conveyed with that advocated recommendation, for example, cite to those guidances around compliance and the like?

A. In the mammogram example, because there are multiple guidelines -- and this again supports my MICI framework because based on some individual differences such as your age, your health status, for example, or history of breast cancer, or cancer as another example, contexts in which the decision is made, you know, whether it is -- whether one has a relationship with a primary care physician or specialist, all of those factors are considered in the design of -- in my research, in the design of multiple communication that is tailored to different audiences.

Q. So I believe you said that there was -- there were some guidances, for

example, about when and how often to get screened for a mammogram, correct?

A. Yes.

Q. Okay. Who issues those guidances?

A. I don't know. I work with physicians, or someone from the medical community, that gives me the information, and I use that information in the messages.

When I have to do an experiment where it's a hypothetical situation, I don't -- you know, I go through a human subject review committee.

When it's in a practical context, there are other reviewers.

Q. So I believe you said you did use that information regarding when and how often to get screened in the messages you designed, for example, in this instance for mammograms, correct?

A. Yes.

Q. Okay. Have you done any similar messaging for pharmaceutical products?

A. Yes.

Q. Does the messages supporting the advocated recommendation for pharmaceuticals often center around compliance?

A. Sorry, I don't understand the question.

Q. Sure.

For pharmaceuticals that you've given advocated recommendations for, has the messaging accompanying the advocated recommendation often incorporated messaging around patient compliance, i.e., you know, staying on schedule with the drug and following -- you know, taking it as prescribed, etcetera?

A. The study that's coming to my mind now as I answer your question, so the answer is yes, and I'm going to qualify it.

It's for a diabetes medication, and my messaging is text messaging, and there are over 60 different types of text messages to remind -- in different formats to remind people to not only stay on schedule for their

medication, but also diet and exercise and screening.

Q. Okay. Thank you for that.

I see that you've also designed some messaging around COVID vaccine hesitancy, correct?

A. I'm sorry, what are you referring to so I can make sure I understand the context?

Q. Are you on some kind of panel related to designing messaging to tackle COVID vaccine hesitancy?

A. I am -- I would not characterize it as a panel. I would say that I am a member of a team that -- of multiple teams. One of the teams, yes.

Q. Sorry.

A. I apologize, I started to explain. You didn't ask that. You just asked am I a member of panel, and it's not a panel, it was a team, and I started describing it, but you may not need that.

Q. Sure. I mean, that was going to be my next question, is, describe to me

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what it is and what your involvement with it is.

A. So I'm on multiple ones. Starting with the research that I'm doing is to, and this is gathering primary data, is to encourage those with COVID-19 vaccine hesitancies to either get vaccinated or to get boosted. It's actually in Massachusetts.

Q. Okay.

A. The second study I'm thinking about is on a team to understand how behavioral economics -- how behavioral economic principles have worked during the pandemic to reduce vaccine hesitancy and to encourage vaccination and COVID-19 booster shots.

And the third one is on a large team organized by the Get the Medication Right X, GTMRx, and that study, or that publication/paper, it is not a peer-reviewed paper, but that paper that is put out by that institution, I was part of a team to think about structural issues, process issues, system issues related to -- and this is why I

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was invited as an expert -- related to MICI, the messaging, individual differences, and the context, and how we might improve those to not only address the current pandemic, but any future pandemics.

Q. Let's take the second one for a moment, and this might be a fruitful example to help me understand what you mean by "behavioral economics."

So I guess draw the connection for me between overcoming COVID vaccine hesitancy and how behavioral economics shaped into that.

A. Right. And I can do that, and actually will also give you insight on the first study, which is based on behavioral economic principles as well.

So one example -- and there are many, many behavioral economists out there and, as I said, made up of people with multiple disciplinary backgrounds, and they have tried different things such as, should we pay people to get vaccinated is one example; should we create a lottery, right,

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to encourage people to get vaccinated; should we frame the message positively or negatively; should we say here's what you gain if you get the vaccine, here's what you lose if you don't get the vaccine. So those are just examples, okay, just to give you a few.

And so, you know, how well have -- and there's a variety of principles, how well have those -- sometimes they call them nudges, a lot of the times behavioral economists call them nudges, the interventions that they use to nudge consumers to take the recommended or advocated actions. But those are examples.

And in the first study that I was describing where I'm actually doing the study here in the State of Massachusetts, we are looking at -- and I'm with a team that is funded -- that sits in the Mass General/Brigham Young Hospital and the Harvard Medical School, and it's a center for -- that's related to use of behavioral economics to improve medication adherence.

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Q. Okay.

A. And -- okay. And this particular -- I'm doing the study with that group, with a subset of that group, and we are looking at some eligible patients or consumers get -- why one should get the vaccine. Some get a message on how to get the vaccine, and that includes the booster. And the third arm is usual care.

And then we track and see which message is the most effective compared to each other, one arm to the other, in a randomized control trial.

Q. Okay. Let me try and see if I understand this.

So I think you mentioned that some of these nudges, for example, for behavioral economics might have been a lottery or to pay people to get vaccinated or what they might gain or lose, for example, losing a job, or something like that?

A. No, gain or loss, sorry, I refer to in a framed message.

Q. Okay. Understood.

So it seems like the baseline for all of that is that it's like a monetary incentive, is that --

A. That is incorrect. Monetary incentives are a subset of the -- as nudges used in behavioral economics. For example, I mentioned frames, you know, you're focused on the benefits or the gains versus the losses are a very popular behavioral economics messaging, not related to money, messaging nudge, and, in fact, the foundation for that is prospect theory, and to prominent economists Kahneman and Tversky, both Nobel Prize laureates, who created the foundation for these and other nudges.

Q. So -- and perhaps monetary incentives could be a subset, I suppose, is what you're saying?

A. Yes.

Q. Okay. Gotcha.

So it's any kind of reward or disincentive, sort of, that affects behavior, I suppose. Is that a more accurate, wholistic way of capturing the idea?

A. I would prefer to rephrase that in terms of benefits and costs. If you think about rewards as benefits, there's some overlap, but not perfect overlap.

And by costs, I am not just referring to monetary costs. There are switching costs, transaction costs, convenience costs. So just want to clarify that we are talking about value as a function of costs and benefits, and those benefits could be a range of benefits.

Q. So, and I'm happy to adopt your terminology there.

It's essentially cost benefit for behavioral economics; what are the benefits of the behavior, what are the costs of the behavior, is that right?

A. (Nodding in the affirmative).

Q. Okay. Flip, if you don't mind, in your report, which is Exhibit 2, to page 17, and that's footnote 36 specifically.

That footnote reads -- let me paraphrase it, I guess. I don't want to read the whole thing. But essentially is what

you're saying there that the -- in ranking -- there's empirical evidence out there that in ranking topics of importance for medical therapy, that consumers and physicians place safety and efficacy routinely at the top of those priorities?

A. So because you are referencing a specific paper, I will say that in this particular paper they look at -- so, for example, there are about 108 consumers, and about 115 or so, a little higher, physicians, that 33 consumers rated safety as the most important topic, the topic of importance for them during initiation of medical therapy. So it's very important to get the details.

And what that means is basically 70-plus consumers did not rate safety as the most important topic during the initiation of medical therapy.

So I just want to make sure that this data is understood correctly, that it will be a range of -- even in the study, a range of consumer responses as to the importance of specific features and the

weight -- sorry, their -- yeah, weight on those features, and that, as I say in my report, is likely to change during the consumers' and the physicians' experience with the consumer taking the drug over time.

Q. Okay. But to -- but what you're saying is the results of that survey show that numerically the most common answer was safety number one, efficacy number two?

A. During the -- topic of importance during the initiation of medical therapy.

Q. Okay. And did you look at the survey design and read the article in citing it in this paper?

A. Yes.

Q. Okay. All right. Thank you.

Do you feel like it was a well-designed survey?

MR. GOLDBERG: Objection to form.

A. I -- it was well designed. It was a good survey. Are there things that could have been -- could have been done

differently? Yes.
BY MR. DAVIS:
Q. Okay. Well, would you agree it was reliable enough for you to cite it in your report?
A. Yes. I mean, you know, it's -- yes.
Q. You wouldn't cite any kind of study or survey or piece of literature in your report that you thought had significant reliability issues, would you?
A. No. The quality of the report is the most important.
Q. So back to your messaging campaigns that you've done, and maybe let's stick with COVID as the example. In the COVID messaging -- vaccine messaging campaigns, how were concerns about safety and efficacy addressed in the communications that supported the advocated recommendation, which was to get vaxed or boosted?
A. I mentioned multiple studies, but I will talk about the question -- I can answer the question for one of those, which

is the three arms of how and why and usual care messaging.
So the messaging goes to people who are eligible for the vaccine or the booster, and I rely on the hospital system and the electronic database, health record database. I am not involved with actually sending out these messages, I only design the messages, but they -- the rest of the team works on the eligibility of the participants.
Q. Okay. So, and you said you were responsible for designing the content of the message, correct?
A. The letter that goes to the patients, yeah.
Q. So what sort of -- in terms of the content of the messages that you designed, what sort of content did you include to address safety or efficacy concerns that may exist amongst the un- or undervaccinated?
A. In these particular messages, to the best of my recall, we use language that the vaccine is -- has been demonstrated

to be shown as effective for mitigating the risk associated with the COVID-19 virus.
Q. Is part of the messaging that the vaccines have gone through an approval process that demonstrated, for example, their efficacy and safety?
A. I'm sorry, can you repeat that?
Q. Was one of the messages that you designed, was the content of one of those messages, did that emphasize the fact that the vaccines had gone through an approval process to demonstrate scientifically their safety and efficacy?
A. I don't recall.
Q. Okay. You sit on the COVID vaccine hesitancy task force, right?
A. One of them, yes.
Q. Let me just mark something as an exhibit then.
MR. DAVIS: This is being handed to the reporter to be marked as Keller 3.
(Whereupon, Keller Exhibit Number 3 was marked for

identification.)
MS. ANDRAS: Since we don't have electronic exhibits, could you for the record and counsel who don't have copies, introduce the exhibit with a little more specificity?
MR. DAVIS: Sure. And I'll do that on the record when I'm going through it with the witness.
BY MR. DAVIS:
Q. For the record, this Exhibit 3 is a -- the cover page to it is a report to the GTR -- GTMRx National Task Force, and it's titled "Background and Resources to Build Vaccine Confidence in the Health Neighborhood" dated March 2021.
Do you see that, Dr. Keller?
A. Yes.
Q. And if you flip to the -- if you go one, two, three, four pages in, do you see your name under "Task Force Participants" there?
A. Yes.
MR. GOLDBERG: John, let me

just say, if you're going to ask about the document, I do think the witness should be able to take a chance to review it.

MR. DAVIS: I mean, I have very limited questions regarding it.

BY MR. DAVIS:

Q. Why don't I ask them, and if you feel like you want to review it, then we can go off the record and you can take a look at it.

A. Can I just stop you for a moment?

Q. Sure.

A. I'm going to ask you to review it regardless of the question you ask, so I don't want you to think that --

Q. Sure.

MR. DAVIS: Why don't we go off the record, then, and you can review it.

MR. GOLDBERG: I think we're going to stay on the record. You can review it. If it takes more than a

few minutes, then we can go off the record. That's the rule in this case.

The rule is that we start reviewing, if it's going to take a long time, then we'll go off the record. But that's what we do in this case.

(Witness reviewing document.)

A. Okay.

BY MR. DAVIS:

Q. And I promise I don't have detailed questions for you on this.

A. Thank you. I --

MR. GOLDBERG: There's not a question pending. Just let counsel ask a question.

BY MR. DAVIS:

Q. So you saw on the first page that this is dated March 2021, correct?

A. Yes.

Q. At the time of March 2021, COVID vaccines were operating under an emergency use authorization, correct, or a EUA?

A. I'm not sure.

Q. Why don't you flip to page, what's numbered as page 6 in the bottom left corner. You'll see some numbering in the bottom left corner, there's a page 6.

Do you see there's a third block bullet, a blue block? Do you see that? Actually yours is black and white. Sorry.

There's a third block there that says, "COVID-19 vaccines have been approved under emergency use authorization."

Do you see that?

A. Yes.

Q. Okay. These vaccines now have full approval, correct, full FDA approval? Is that your understanding?

A. I'm not sure.

Q. Okay. Do you see that there's a third bullet under that bullet I pointed out to you, a smaller bullet that says, "Others warn that EUAs exacerbate the deterioration of the public's confidence in science"?

Do you see that?

A. I need a moment to just look at the context.

(Witness reviewing document.)

A. Okay.

Q. Was that one of the findings of this task force that's in this report that you sat on, was that among the vaccine hesitant there was -- some of that was related to the fact at the time of this report that the vaccines had not undergone a full approval process?

MR. GOLDBERG: Objection to form. Vague, mischaracterizes the document.

A. Could you please be more specific?

BY MR. DAVIS:

Q. Did you assist in drafting this report?

A. I was a member of the task force that reviewed certain sections of the document, and participated in discussions on the creation of the document.

Q. Let me just tell you where I'm

going with this, which is that, would you agree -- and maybe we can bypass all of this. Would you agree that consumers and physicians look at approval by the regulator as an important piece of information to consider in making a consumer choice?

A. You need to be more specific. Those are two questions.

Q. What are the two questions in there?

A. You said "consumers and physicians."

Q. Okay. Well, let's take it from the consumers first. So the same question, just for consumers.

A. Could you repeat the question?

Q. Sure.

Would you agree that consumers in making choices regarding medications or medical therapy view approval by the regulator as an important piece of information?

A. There is a range of consumer responses, as I have explained in my report,

in various section -- subsections of Section IV in my report, such as IV.B, that using different decision rules, compensatory and non-compensatory, some may and some may not.

Same with the MICI factors in Section IV.C of my report, some consumers may pay attention to the information or approval from the FDA as part of the messaging that they consider, and some may not.

For example, they may pay much more attention to their individual health status or the context such as their relationship with the physician, rely on the physician to give them guidance.

Q. Let's take it back to the COVID vaccines for a second.

You're currently, I think you testified, doing some messaging encouraging vaccination and boosting, correct?

A. Yes.

Q. Okay. Is part of the substance of that message that's being conveyed now that these vaccines have full safety and efficacy endorsement by the FDA; they're, in

other words, approved as safe and effective by the FDA? Is that part of the messaging?

A. I do not recall. My task in this project is to focus on the how versus why components of that message. There are other team members that are focused on other aspects of who gets the message and the context in which they get the message.

Q. Okay. Let's transition.

MR. GOLDBERG: John, if we are transitioning, can we take a break?

MR. DAVIS: Sure. Yeah, that's fine.

THE VIDEOGRAPHER: Off the record at 10:43.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: Back on the record at 11:04.

BY MR. DAVIS:

Q. Do you have any understanding of how generic drugs specifically get approved in the US?

A. No.

Q. Do you have any understanding of what -- how generic drugs are supposed to compare to their brand counterparts?

MR. GOLDBERG: Objection to form. Vague.

A. Please clarify.

BY MR. DAVIS:

Q. Sure.

What is a generic drug, can you tell me that?

A. From a marketing perspective, a generic drug is an unbranded drug.

Q. And compared to branded drugs, what are unbranded drugs supposed to be in comparison to them?

A. One thing they're supposed to be is cheaper.

Q. Okay. Do you understand that they're supposed to be therapeutically equivalent?

A. In a prescription drug context, yes.

Q. In fact, would you agree that many aspects of our healthcare system rely on

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an assumption that generic drugs are therapeutically equivalent to their brand counterparts?
A. Could you please repeat?
MR. DAVIS: Could you repeat the question?
(Whereupon, the reporter read back the question:
QUESTION: In fact, would you agree that many aspects of our healthcare system rely on an assumption that generic drugs are therapeutically equivalent to their brand counterparts?)
MR. GOLDBERG: Objection. Vague.
A. Many aspects of our healthcare system, it's too -- it's not specific enough for me.
BY MR. DAVIS:
Q. Okay. Are you familiar with automatic generic substitution at the pharmacy level as a concept?
A. Could you repeat that?

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Q. Are you familiar with automatic generic substitution at the pharmacy level as a concept?
A. What do you mean "as a concept"?
Q. Well, let's take that off.
Are you familiar with automatic generic substitution at the pharmacy level?
A. I know that -- I don't know who does it, but I know that sometimes when you -- as a consumer when you expect a branded drug you are given a generic.
Q. Well, it's regardless of whether a consumer expects a branded drug or not, the substitution occurs, does it not?
MR. GOLDBERG: Objection to form.
A. I don't know.
BY MR. DAVIS:
Q. Okay. Do you have any familiarity with how reimbursement or formulary decisions are made in response to the market entry of a generic vis-à-vis the brand?

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A. No, I am not an expert on that.
Q. Okay. Are you familiar with the fact that when a physician writes a prescription on a prescription pad, even if the physician writes the brand name, that oftentimes if there's a generic, the generic will be dispensed because of generic substitution laws?
A. I don't have an opinion on that.
Q. And I believe you said you don't know what generic manufacturers have to demonstrate to the FDA to get their generic drugs approved for sale in the US, correct?
A. I do not recall saying that.
Q. Okay. Well, then, let me ask it then.
Are you aware --
A. Can you please repeat it?
Q. Are you aware of what generic drug manufacturers have to demonstrate to the FDA in order to get their generic drugs approved for marketing and sale in the US?
A. I am not an expert. I don't

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have an opinion.
Q. Well, the question is do you know.
A. No.
Q. Are you familiar with the fact that generic pharmaceutical manufacturers do not routinely engage in promotional activities for their drugs?
A. I do not know.
Q. When I refer to FDA-approved labeling, do you know what that means?
A. Could you be more specific?
Q. Sure.
Do you know what an FDA-approved label is?
A. No.
Q. Have you looked at any FDA-approved labeling for any of the generic valsartan products at issue in this case?
A. I have looked at some labels of valsartan. I do not know if they are FDA-approved or not.
Q. In general terms, the labels that you looked at, what kind of information

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did they contain?
A. To the best of my recall, they contained the name of the drug, the dosage, the manufacturer, and the country of manufacture.
Q. Did you see any section in those labels that had warnings or contraindications or side effect information, anything like that?
A. I do not recall.
Q. Okay. What about a listing of ingredients?
A. I do not recall.
Q. Would you agree that the purpose of those labels that you reviewed was to provide information regarding the drug?
A. Please define "information."
Q. Well, sure. I mean, you mentioned what it is, who manufactures it, things like that. Would that in your mind constitute information regarding the drug?
A. In my mind it would constitute some information regarding the drug. There could be other information regarding the drug

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that is not on the label or that I do not recall was on the label.
Q. If the purpose of FDA-approved labeling was to provide information to consumers and physicians regarding the drug, what's in it, potential side effects, etcetera, would you disagree with that?
A. Please repeat the question.
Q. Would you disagree with the proposition that FDA-approved labeling is designed to provide to consumers and physicians certain information regarding the drug?
MR. GOLDBERG: Objection to form. Foundation.
A. I cannot answer that question.
BY MR. DAVIS:
Q. So you don't know the purpose of FDA-approved labeling?
A. That was not the question you asked, but is that the question you're asking now?
Q. Well, that's my new question, yes.

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A. No.
Q. Have you ever studied health messaging to consumers or physicians regarding generic drugs vis-à-vis brand drugs?
MR. GOLDBERG: Objection to form. Ambiguous.
A. Could you repeat that, please?
BY MR. DAVIS:
Q. Sure.
Have you ever studied any kind of health messaging to consumers or physicians regarding generic drugs?
A. Not that I recall.
Q. Okay. Not in your work in this case, and not ever, is that your testimony?
A. I don't understand the question.
Q. Sure. I'm trying to clarify whether your answer is you haven't looked at that in this case or you haven't looked at that at all ever.
A. Okay. So can you repeat the question again so I understand the context?

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Q. Sure.
The question that you said "no" to was whether you had had any occasion to look at health messaging to consumers or physicians regarding generic drugs, and I believe you said "no" to that, right?
A. I'm going to qualify. If by "health messaging" you are also including what the FDA said about generic valsartan, then I did have a chance to look at that for this case.
Q. I'm talking about from a general proposition, so regarding generic drugs generally, their uses, their benefits, what they are, etcetera.
Have you ever looked at any generalized messaging to physicians or consumers regarding generic drugs as a therapeutic sort of class?
A. Not that I recall.
Q. Okay. Not in this case?
A. I can't answer the question. Could you repeat the question?
MR. DAVIS: Could you repeat

the question?
(Whereupon, the reporter read back the following:
QUESTION: I'm talking about from a general proposition, so regarding generic drugs generally, their uses, their benefits, what they are, etcetera.
Have you ever looked at any generalized messaging to physicians or consumers regarding generic drugs as a therapeutic sort of class?
THE WITNESS: Not that I recall.
QUESTION: Okay. Not in this case?)
A. So the challenge I'm facing is you asked about as a general proposition, and I answered, and then now you're saying "not in this case," and so I'm just trying to make sure I understand the question, which is a very specific proposition.
BY MR. DAVIS:
Q. Okay. So let me just try it

again.
In this case, have you looked at any generalized messaging to physicians or consumers regarding generic drugs generally as a therapeutic option or class?
MR. GOLDBERG: Objection to form. Ambiguous.
A. Can you give me an example of what that messaging would look like so I'm better able to understand?
BY MR. DAVIS:
Q. Sure.
MR. DAVIS: I'm handing to be marked as Exhibit 4 a 14-page document.
(Whereupon, Keller Exhibit Number 4 was marked for identification.)
MR. HONIK: Is this 16, John?
MR. DAVIS: Yes.
MS. ANDRAS: Can you describe for the record for counsel who do not have copies of these what document you've marked?

MR. DAVIS: Sure. For the record, this is an FDA resource from the FDA's website titled "Generic Drugs: Questions and Answers."
BY MR. DAVIS:
Q. Have you ever seen this document before, or this content on the FDA website?
A. I would like to check my report. It looks familiar, but I'm not sure.
Q. Sure. If you want to check your report, that's fine.
(Witness reviewing document.)
A. Okay. Thank you.
Q. You don't see it in your report, do you?
A. I do not.
Q. Okay. And is it your testimony that you've never seen this before or reviewed it on the FDA's website?
A. Correct, yes.
Q. Okay. This, Dr. Keller, is an example of, like you asked for, of what I'm talking about here. Do you see that this is

a sort of general resource put out by the FDA titled "Generic Drugs: Questions & Answers"?
A. That's what the title says, yes.
Q. And it has some subsections like, "What are generic drugs? How does the FDA ensure generic medicines work the same as brand-name medicines?"
Do you see that?
A. I see that on the first page, but I have not had a chance to review this document, so...
Q. Well, I only provided this as an example.
So as an example of what I was talking about prior to showing you this document, have you reviewed or had any occasion to review any kind of general resources similar to the one that I've marked as Exhibit 4 that have to do with generic drugs generally?
A. I cannot answer that question about how -- whether I've reviewed anything similar without knowing what this is to make

that comparison. I need time to review this document.
Q. Okay.
(Witness reviewing document.)
MR. GOLDBERG: Dr. Keller, if you're going to go further, we can go off the record for a minute until you finish, okay? That's fine.
Can we go off the record?
THE VIDEOGRAPHER: Off record at 11:25.
(Off the record.)
THE VIDEOGRAPHER: Back on the record at 11:30.
BY MR. DAVIS:
Q. Okay. Dr. Keller, you had a chance to flip through every page of that document, correct?
A. Yes.
Q. Okay. And you read it, you didn't just flip the pages?
A. I, I'm going to use the word surveyed, or looked broadly over would be a better term for it. I tried -- it was not a

lot of time. I tried to look at it as carefully as I could.
Q. Okay. Have you ever seen a -- you see that this is a Q&A titled "Generic Drugs: Questions & Answers"?
A. Yes.
Q. Have you ever seen a Q&A or an FAQ document in any context?
A. Yes.
Q. And this is an example of one of those, but for generic drugs, put out by the FDA, correct?
A. Yes.
Q. Okay. Would you characterize this as an educational resource having looked at it?
A. You need to be more specific. What does "educational resource" mean?
Q. Well, for example, did you -- in reading it, were you able to educate yourself a little bit on generic drugs?
A. Yes.
Q. Okay. Thank you.
Is the -- having looked at it

now, would you agree that the basic message that's being put out by the FDA is that generic drugs are just as safe, effective, and high quality as their brand name counterparts?
MR. DAVIS: Could you repeat the question?
(Whereupon, the reporter read back the following:
QUESTION: Having looked at it now, would you agree that the basic message that's being put out by the FDA is that generic drugs are just as safe, effective, and high quality as their brand name counterparts?)
A. Yes, from -- more true, yes, from the FDA's perspective. No, that would not be my uniform takeaway from a consumer perspective.
BY MR. DAVIS:
Q. Well, what's unclear about the first page, the little graphic that the FDA provides, where it says "Generic, Safe, Effective, High-Quality" all with checkmarks,

"Brand-Name, Safe, Effective, High-Quality," all with checkmarks?
Do you see that?
A. Yes.
Q. Okay. And the message that the FDA is trying to convey is that generic drugs are just as safe, effective, and high quality as their brand name counterparts. Is that not the message the FDA is trying to convey here?
A. You are correct that those checkmarks appear on the first page. But when I read the information on subsequent pages, as I read information such as The generic may act differently from the brand name, for example, in absorption.
Q. So you disagree that the FDA is attempting to convey a message here that generic drugs and brand name drugs are interchangeable?
A. No.
MR. GOLDBERG: Objection to form.
A. Please specify.

BY MR. DAVIS:
Q. Okay. Well, let's start with my prior question.
You agree, yes, that the FDA's intended message with this document, and specifically with this graphic on the first page, is that generic drugs are just as safe, effective, and high quality as their brand name counterparts?
A. Incorrect. I said that the graphic displays that. But if you said the document, which I'm assuming you're referring to the document before me, that that has information in there, and I gave you only one example from my quick read or survey of the information that led me to believe that they are not the same.
For example, on effectiveness, I just told you that I read that the absorption for generics may be different from brand products, brand name products.
Q. Do you know what "absorption" means?
A. Again, I need to look at the

document.
Q. Well, why don't I take you to page 12 of the document. Do you see the heading "How Does FDA monitor side effects or safety issues with generic medicines?" Do you see that heading on page 12?
A. Before I answer that, can I assume when you ask a different question without my answering the previous one that you are striking it?
Q. Sure. Yeah. I'm moving on.
A. Okay.
Q. I might come back to it.
So do you see the header there on page 12?
A. "How Does FDA monitor side effects or safety issues with generic medicines?"
Q. It says there that the "FDA takes several actions to ensure safety and quality before and after a new or generic medicine is approved."
Do you see that?
A. Yes.

Q. And then it reads further down that part of that is ensuring, last two lines, "that every generic drug is safe, effective, high quality, and substitutable to the brand name drug."
Do you see that?
A. I do not, sorry. Where is that?
Q. That would be the last two lines of the first paragraph.
A. Oh, the last two lines, okay. I went to the bottom of the page.
Yes, I see that.
Q. Okay. And so the FDA is essentially stating in text there what it stated in the graphic on the first page, correct?
A. I do not view them the same.
Q. What's different to you?
A. So for me, when I see a graphic with the checkmarks, the checkmarks look the same, and it appears to be the same for generic and brand name.
But when I look at the text

here, the text that you asked -- that you referred to for this question, when it says that the word "to ensure" is not telling -- they're saying they're trying their best, that's my interpretation of "ensure," but that does not mean that they are, for example, in a marketing context doing something more, like saying it is the same.
Q. Well, they're not saying anything about trying their best here, they're saying that they "ensure that every generic drug is safe, effective, high quality, and substitutable to the brand name drug." They say that right there, correct?
A. They say that. You asked me why I didn't think it was the same in the graphic and the document, and I'm telling you that it appears to me to be the same, brand and generic on those three features in the graphic, but not in the document.
And the reason it is not for me the same in the document is because of the language that is used here, specifically in this particular case in the sentence you

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asked me to read on ensure, that makes me believe that it may not be the same, or that FDA is doing something to ensure that it is the same, but it's not saying it is the same.

Q. Okay. Do you know what would happen, for example, if the FDA, despite their best efforts, found out that a generic drug was not safe, not effective, or not high quality? Do you know what would happen in that case?

A. I'm not an expert. I cannot tell you for sure.

Q. Okay. Go to page 2 of the document, if you don't mind.

A. The same document?

Q. Same document. Exhibit 4 for the record.

That first question there that appears in this Q&A is, "What are generic drugs?"

Do you see that?

A. Yes.

Q. And it says, "A generic drug is a medication created to be the same as an

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already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use."

And then if you go down to the last sentence you'll see, "In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."

Do you see that?

A. Yes.

Q. Okay. Who is the "you" there in this document? Who do you imagine the FDA is referring to as "you" here?

A. Whoever is reading the message.

Q. Or whoever is taking the generic medicine, as they say, correct? "You can take a generic medicine."

A. No. It says you can take it. It doesn't mean they're taking it.

Q. Do you read "you" here as being directed to the consumer, the person who takes the generic medicine?

A. I need to look at the document again.

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So you're referring to the last sentence, "In other words, you can take a" -- yes, I see that, yes.

Q. And the "you" there is the patient, correct, the consumer?

A. The consumer for whom this medicine is applicable, right.

Q. And to borrow some terminology you used before, this would be the advocated recommendation, correct, by the FDA regarding generic drugs?

A. Yes and no. Yes if this document was defined as a communication message to consumers; no because it's not clear to me what the specific advocated action is.

Q. What makes you think that this might not be a document directed to consumers?

A. I don't know. I don't know the context in which this was created, or when it was created, and for whom it was intended. I don't have that information.

Q. You can't derive that from

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having just read this?

A. As a health communication expert, I would not like to make that determination.

Q. Okay. Well, you did agree with me earlier that the "you" in that sentence was directed towards the consumer or patient, correct?

A. I said that it was directed at a person for whom a decision about a generic or brand name selection was applicable.

Q. And that would be a consumer or a patient, correct?

A. If a consumer was considering whether -- what the difference was, they might or might not seek this information. There would be a range.

Q. And that advocated recommendation there that we read, "you can take a generic medicine as an equal substitute for its brand-name counterpart," that's founded on the assumption that the generic drug and the brand-name drug are both safe, effective, and high quality, and

substitutable as we saw on page 12 that we just read, correct?

MR. GOLDBERG: Objection to form. Foundation.

A. That is not how I interpret that.

BY MR. DAVIS:

Q. What's incorrect about my interpretation?

A. I'll highlight one.

Q. Sure.

A. First, very simply, this information appears before page 12, so I don't know whether this was based on what is in page 12, especially if it appears before. I'll stop there.

Q. Okay. Well, I mean, what about what appears just before the sentence on page 2, "A generic drug is a medication that is created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, intended use," those various things, do you

think safety, efficacy, and high quality are encompassed by those terms in that sentence?

A. No.

Q. You don't?

A. No.

Q. Okay. Explain to me why not.

A. From -- as a consumer expert, consumer health decision-making expert, one example would be that for me, efficacy is broken down into self efficacy and response efficacy.

Response efficacy is, you know, does the drug do what it's supposed to do; self efficacy is, you know, will the drug work for me.

Q. Okay. You testified earlier that you have very little knowledge of what's required for drug approval in the US, correct?

A. Yes.

Q. Okay. So you really don't know what the FDA means by "efficacy" in terms of approval of a brand or generic drug, is that correct?

A. Actually please repeat that question.

MR. DAVIS: Can you read the question back?

(Whereupon, the reporter read back the question:

QUESTION: Okay. So you really don't know what the FDA means by "efficacy" in terms of approval of a brand or generic drug, is that correct?)

A. I'm not going to form an opinion on that.

BY MR. DAVIS:

Q. Okay. You're a health communication expert, correct?

A. I'm an expert on consumer decision-making with a focus on health.

Q. In fact, you testified today that you've designed some of the content of the messages to consumers, correct?

A. The content of some of the health communication to consumers.

Q. Correct.

And having just leafed through this document here, Exhibit 4, using your -- you know, relying on your expertise as someone who does this for a living, what is the message that the FDA is trying to impart with this Q&A document that's Exhibit 4?

A. There's a lot of information here. I would not be comfortable telling you what the FDA's intentions are or what they are trying to impart.

Q. You don't think they're trying to impart to a consumer or patient that they can take a generic medicine as an equal substitute for its brand-name counterpart?

A. I've tried to answer that question. As a communication expert, I'm leery of any sentence that starts with "in other words."

Q. Aren't they -- I mean, the in other words to me is the FDA trying to take a complex regulatory system of drug approval and put it in simple terms for a patient or consumer. Do you not read it that way?

A. I do not, because I'm putting

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on my consumer hat, and I see a lot of things here that -- route of administration, etcetera -- that are not -- may not be familiar to some consumers, they may be familiar to other consumers, but I'm going to predict a range of what consumers take away from that message.

Q. Flip to page 6. You'll see some pagination in the bottom right corner of page 6 of 14. The header there is "What standards must generic medicines meet to receive FDA approval?"

Do you see that?

A. Yes.

Q. Okay. And I think you testified earlier that you didn't know what an ANDA was. I'll represent to you that an ANDA is an Abbreviated New Drug Application, which is what a generic manufacturer submits to the FDA for approval of its proposed generic medicine to be marketed in the US.

Do you understand that?

A. I see here it says "drug companies," it does not say "generic

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manufacturers." But I see the rest.

Q. Well, I'll represent to you that an ANDA, or A-N-D-A, Abbreviated New Drug Application is what a generic manufacturer submits to market a generic drug, okay? And then it says below that, "An ANDA must show the generic medicine is equivalent to the brand in the following ways:"

Do you see that?

A. Yes.

Q. And then there's some bullet points that start on 6, go down to 7 and 8, and conclude on page 9, I believe.

Do you see that?

A. Yes.

Q. Okay. If you flip to page 7, you'll see that the last bullet point there says that "It" -- being the generic drug -- "is manufactured under the same strict standards as the brand-name medicine."

Do you see that?

A. Yes.

Q. Okay. Did you have any idea

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that that was a requirement for ANDA approval of a generic drug to be marketed in the US?

A. I saw that in Dr. Conti's report.

Q. Do you have any reason to disagree with what's in this bullet point here --

A. NO.

Q. -- on page 7?

Let's say that the FDA, that you've worked -- strike that.

You've worked with regulatory bodies in the US, correct, like, for example, the CDC?

A. Yes.

Q. Okay. Let's say that the FDA came to you and said, Dr. Keller, we've noticed that consumers/patients in the US, there's a distrust for generic medicines, we want you to design a messaging campaign to advocate -- to create an advocated recommendation that patients can trust their generic drugs.

Are you following me?

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A. Mm-hmm.

Q. Okay. Would not one of the messages you would include in that advocated recommendation to patients, would not one of those messages be exactly what the FDA is emphasizing here, which is that generic drugs are subject to -- are substitutable as we saw on page 12, that they are safe, effective, high quality as we saw on page 1, and that they are manufactured under the same strict standards as the brand-name medication as we see on page 7?

Would those not be messages you might want to include in your communication to patients to overcome that objection to generic drugs?

MR. GOLDBERG: Objection. Ambiguous, compound.

A. I don't know how -- I stopped counting how many questions there were in that question. Could you please break it down?

BY MR. DAVIS:

Q. I mean, I thought it was quite

clear, to be honest.

Would you not want to include those messages that we've called out and read in this document in your advocated recommendation to consumers that the FDA in this hypothetical assignment is giving you?

MR. GOLDBERG: Same objection.

A. I cannot answer that question. I was even flipping pages, and I'm on page 12, and I cannot in my quick survey even find the word "substitutable," so I cannot answer that question.

BY MR. DAVIS:

Q. We read it. It's the last sentence of the first paragraph there. "Ensure that every generic drug is safe, effective, high quality, and substitutable to the brand-name drug."

A. Thank you.

Q. Would you not want to include those messages that we've read in this document just now in your communication to consumers/patients in this hypothetical assignment from the FDA?

A. If the FDA came to me with this assignment, I would need a lot of information on consumers to make a decision about the different types of effective -- the different types of messages that may be effective for different types of consumers based on -- I'll just give you examples because it was a long question -- where and how and from whom they would trust the message, or message factors, I'm using MICI, their individual differences, for example education level, language fluency, etcetera; the context in which they were making this decision, for example with a trusted physician or a new physician; and the interaction of those factors.

I would also want to know information on the features that patients take into account when they're making such a decision.

I testified earlier about the -- how I create communication to create and communicate value to consumers, so I would need to know what kind of benefits different consumers are seeking in the

communication and what kind of costs I need to address or overcome in the communication.

My research shows that these factors vary across individuals, and all of my work and my report supports, along with many, many others, the need to get this information in order to tailor this communication so that I can understand how consumers would evaluate my advocated recommendation, "my" as in in my task.

Q. Do you think there's a single consumer out there in the US who if they went to the pharmacy and got dispensed a generic drug, that they would not want that generic drug to be substitutable to the brand-name drug?

A. As a consumer behavior expert, you never want to make an assumption about uniformity on consumer reactions or valuations of work.

Q. So are you saying that you think it's a possibility that there are consumers out there who, when they went to the pharmacy to fill a prescription and they

got dispensed the generic drug, that they would not want that generic drug to be substitutable to the brand-name drug?

A. I'm going to say yes and no.

I will say yes, they will expect that they are getting something from the pharmacy that the pharmacist or someone else who made the decision believes is similar.

No as in they don't know whether it would be similar for them because they don't -- they have more information and agency on what has worked for them in the past, what has not worked for them in the past, the individual factors that I'm talking about, how they take their medication, you can't make an assumption, you know, are they used to taking it once a day, multiple times a day, whether they take it with food, without food.

There are so many additional factors where they would have questions about similarity or substitutability, because from a consumer behavior perspective it's not what

someone else is saying is similar, it's how they're experiencing similarity, or if their experience is the same.

Q. If a generic drug were not substitutable to the brand-name drug, do you have any idea whether that would be a non-approved drug?

A. I am not familiar with the FDA regulations, so I cannot answer that question.

Q. Have you ever designed any kind of messaging to consumers or physicians that advocated that they take or prescribe unapproved medications?

A. No.

Q. Have you ever designed any kind of messaging to consumers or physicians that they take or prescribe adulterated medications?

A. Not to my knowledge.

Q. Misbranded medications?

A. Please define "misbranded."

Q. Do you know what misbranded means?

A. From Dr. Conti's report I have a general understanding.

Q. And what's that understanding?

A. That the -- what is in the brand -- in the product is not the same as what is on the description.

Q. Right. That the label is false or misleading in any particular, correct?

A. Well, no, I will not go that far. I will not say the label is false or misleading. That will vary by the consumer.

Q. Well, you don't know whether that's, in fact, the definition that congress provides for misbranding.

A. Agreed, I'm not an expert.

Q. Okay. Have you ever designed any kind of communication or messaging to physicians or consumers that they take or use any kind of medication that was illegally sold or distributed to them?

A. Not that I'm aware of.

MR. DAVIS: I'm at a transition point. Do we want to take lunch, or do you want to keep going?

MR. GOLDBERG: Up to you. I know lunch is here.

THE WITNESS: I'm indifferent.

MR. DAVIS: Why don't we go off the record for a second.

THE VIDEOGRAPHER: Off the record at 12:01.

(Whereupon, a luncheon recess was taken.)

AFTERNOON SESSION

THE VIDEOGRAPHER: Back on the record at 12:40.

BY MR. DAVIS:

Q. Okay. Dr. Keller, your report, Exhibit 2, would you mind pulling that out? I want to ask you --

A. You mean Appendix B?

Q. No, no, just your report, which is -- I've marked as Exhibit 2.

A. I'm so sorry. I misunderstood.

Q. Not a problem.

So I just want to ask a clarifying question regarding your assignment on paragraph 1, which is on the first page.

You say, "I have been asked by counsel for Defendants to review health care decision-making and how valuation of VCDs should be viewed in light of the voluntary recall of VCDs in 2018 and '19."

Are you with me there?

A. Yes.

Q. Okay. I'm just trying to

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understand the word "and" there. Is that two assignments, or is that one assignment?
A. I'd say that the assignments are connected.
Q. Okay. And what do you mean by that?
A. That I reviewed the healthcare decision-making literature to help inform my opinion on how consumers -- the range of consumer responses for those taking the VCDs, how they might respond, if at all, to the recall of the VCDs in 2018 and 2019.
Q. Okay. So when you say healthcare decision-making there, you're referring to the portion of your report discussing and setting forth compensatory decision analysis and noncompensatory, and non-MICI, that acronym, that's what you mean by healthcare decision-making?
A. Could you please repeat that question?
Q. Sure. I'm just trying to connect your assignment to the substance of your report.

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So when you say you've been asked by counsel for defendants to review healthcare decision-making, am I to understand the healthcare decision-making there to refer to the portion of your report that discusses the compensatory decision rule and noncompensatory decision rule that you explain in your report, as well as the MICI factors?
A. Yes and no. The yes is that I have reviewed the literature on the compensatory/noncompensatory decision rules, and reported a subset of that literature as well as the MICI framework, but not just for the -- how consumers might react to the recall of the VCDs in question, because there's a second part of the paragraph, which I also reviewed the literature to evaluate from a consumer's perspective Dr. Conti's claim, in particular that the VCDs at issue were worthless to consumers as a result of the recall.
Q. Well, and I'm -- we'll get to that. I'm just trying to connect your

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assignment to what's in your report.
And so you reviewed healthcare decision-making as a general proposition from a consumer and physician standpoint, correct?
A. Yes.
Q. Okay. And that's discussed in sort of your general outline of compensatory and noncompensatory decision rules and MICI, correct?
A. Yes.
Q. Okay. And then you applied that framework to the facts of this case, or attempted to, correct?
A. No, to perform my task that you just highlighted in the first paragraph.
Q. So are you telling me you did not apply that framework to -- or attempt to apply that framework to the facts of this case?
A. I didn't say that. I think I said just the opposite.
Q. Well, that's what I was asking you to confirm, and you wouldn't confirm it.
A. Yes.

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Q. So let me rephrase it so we're on the same page.
You then applied the compensatory/noncompensatory decision rule analysis and MICI to the facts of this case, correct?
A. I would not go so far as to the facts of this case. There are many facts of this case that I -- that are not part of my task.
Q. So are you saying you did not apply -- what did you -- let me ask it this way.
What did you apply those healthcare decision-making concepts that you outlined? What did you apply those to?
A. The compensatory/noncompensatory rules for how consumers make a value judgment based on the alternatives they consider, the weights of the different attributes they consider, and the ratings that they give to those attributes in different combinations, and the MICI factors were used by me or applied by me

to make an assessment of how consumers might respond to the recall -- to the recall VCDs, and to answer the question would all consumers uniformly believe that the recall VCDs were worthless.

Q. You're not a physician, are you?

A. No.

Q. Okay. And you're not a public health official?

A. Define "public health official."

Q. Like you don't work for the FDA or the CDC, or you're not a public health official, are you?

A. I am not a full-time employee of a government agency.

Q. Okay. And you wouldn't hold yourself out as being an expert on the substance of any medical decisions, treatments, that a physician might make or the FDA might recommend, correct?

A. Please define "substance."

Q. Sure.

You wouldn't be -- you wouldn't step into the role of a physician and say -- to tell consumers do this or don't do this from a medical standpoint, would you?

A. Please define "from a medical standpoint."

Q. Exactly what physicians do every day when they talk to their patients, you wouldn't step into that role, would you?

A. As shown in my report, and one recent project comes to mind, I provide communication strategies for physicians to tailor their messages and recommendations to their patients.

Q. But you wouldn't come up with the recommendation itself; you're coming up with the messaging around that recommendation, correct?

A. I'm having a hard time separating some of those, or trying to understand what you're getting at.

Q. It's a simple question.

You don't practice medicine, do you?

A. No.

Q. And as far as the medical substance of medical care, you don't step into the role of the physician and actually advocate of your own accord treatment decisions, do you?

A. No.

Q. Okay. And same thing for -- same question for public health officials, you don't substitute your judgment for that of the regulator, for example the FDA, in any of the decisions that are within its regulatory ambit, do you?

MR. GOLDBERG: Objection to form. Ambiguous.

A. I'm not clear on the question.

BY MR. DAVIS:

Q. Okay. I mean, I asked a variation of that question right before lunch, which was, you would never advocate in any message that physicians take or a patient -- physicians prescribe or patients take unapproved medications, for example, would you?

A. I do not recall that question, so...

Q. Well, let me ask that question again.

Would you ever advocate in any kind of health communication messaging that a physician prescribe an unapproved medication?

MR. GOLDBERG: Objection to form.

A. Please repeat that.

MR. DAVIS: Can you read the question back?

(Whereupon, the reporter read back the question:

QUESTION: Would you ever advocate in any kind of health communication messaging that a physician prescribe an unapproved medication?)

MR. GOLDBERG: Objection to form. Ambiguous.

A. Unapproved by?

BY MR. DAVIS:

Q. You understand that drugs have

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to be pre-approved, correct?
A. So I just want to make sure that this is not unapproved by the physician or somebody else. I just want to be clear.
Q. Yes. When I say "unapproved medication," I'm talking about FDA approval that's required for all drug products in the US.
So the question is, would you ever in any of your health communication messaging advocate for the use of an unapproved medication?
A. In this particular case I have reviewed and included in my report materials where physicians continued to ask -- to recommend to their patients that they take a VCD that was recalled.
Q. That's not answering my question.
A. So if I -- you said are there any circumstances. So just like your previous hypothetical that if the FDA asked me to create a communication, if a physician asked me to create a communication I would

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not -- I would try to say no, I'm not going to do that because the FDA has not approved this communication. And that's why I gave you the example I did.
If there is some understanding that they should continue to take the medication, then I would help them do that.
Q. Well, I'm not -- you're not following the thrust of my question. I'm asking you about --
A. Sorry.
Q. -- a drug that was never approved.
A. Oh, I'm sorry, I didn't hear never approved.
Q. That's what I mean by "unapproved medication," something that wasn't approved.
So would you ever advocate -- and this gets to my broader question about you not substituting your judgment or making any kind of public health judgments that are preserved for the regulator, correct? And the question is, would you ever advocate for

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the use of an unapproved drug? And by that I mean something that was never approved by the FDA.
MR. GOLDBERG: Objection to form. Ambiguous, speculative.
A. I don't ask those questions. There is a review process for the work that I do, and I leave it to others to make those determinations.
I have a very specific role that I play in designing the message communication, and that role does not require any expertise or knowledge on my part on regulatory approval or unapproved or anything of that spectrum.
Q. Right. And that's simply my question, is you rely on those people to do their job, right? You rely on the FDA to do the business of public health regulation, correct?
A. That is not what I said. You asked me in my projects, in all my previous work, you know, do I -- this is my understanding of what you asked me, do I

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ensure, or do I seek information or -- sorry, I'm sorry, it was dinging away and I didn't --
MR. GOLDBERG: Can we just go off the record for a second?
THE VIDEOGRAPHER: Off record at 12:54.
(Off the record.)
THE VIDEOGRAPHER: Back on at 12:54.
A. So I agree that that was not my job on these projects. I'm not agreeing that it's the FDA's job. I'm saying, depending on the project, I don't know who takes care of different aspects of the job.
BY MR. DAVIS:
Q. Let me ask it this way.
Have you ever designed any kind of messaging that's health-related to consumers or physicians that you knew was inconsistent with what the FDA's position was on that very subject?
A. I have never checked to see whether what I'm designing a message -- a

health message for has or has not been approved by the FDA.

Q. Well, I'm not saying approved by the FDA. I'm saying, have you ever done that, have you ever designed a message related to healthcare that goes out to a consumer or physician that you knew was inconsistent with the FDA's position on that very same subject matter?

A. I'm not an expert on the FDA, and that is not something that I would seek or look for information on before I designed the message.

Q. Okay. You wouldn't hold yourself out as an expert on how to appropriately address from a medical care standpoint a patient who was taking nitrosamine-contaminated VCDs, would you?

A. Please repeat that question.

Q. You wouldn't hold yourself out as an expert on the medical care decisions that a physician and patient may want to make in response to a patient's exposure to nitrosamines in their valsartan, would you?

A. I'm not an expert in that. I would not have an opinion.

Q. Okay. And when you discuss healthcare decision-making, for example in paragraph 1 of your report that we just read in your assignment, you're not discussing the decisions of congress and the FDA regarding structural aspects of our healthcare system, are you? That healthcare decision-making you're focused on here is related to physicians' and consumers' choices, correct?

A. It's more specific. It's related to how consumers, sometimes on their own and sometimes in conjunction with their physicians, would assess the worthiness or value of a drug, and in this particular case the recalled VCDs.

Q. Okay. Let's stick with my question, which is, you're not critiquing or in any way discussing in your discussion of healthcare decision-making the structural aspects of our healthcare system that congress and the FDA have set up, are you?

MR. GOLDBERG: Objection to

form. Ambiguous.

A. I don't know what those structural elements are, and I'm not an expert on what congress and the FDA have -- the system that they've created, and I'm not going to give you an opinion on that.

BY MR. DAVIS:

Q. Right.

And you're not taking any issue with any of that is my question, correct?

A. I'm -- if I'm not an expert on it and I'm not giving an opinion on it, I should not be interpreted as taking issue with it. I have nothing to say about it.

Q. Okay. You -- continuing in that assignment paragraph, you say you've been tasked with evaluating certain assertions from Dr. Conti, particularly her claim that VCDs in this case were worthless.

Do you see that?

A. Yes.

Q. And you call her -- you call her analysis -- you basically say that she's applying a non -- uniform noncompensatory

decision rule, do you not?

A. I do not say that.

Q. Take a look at paragraph 9 of your report, first bullet point. You say in the middle of that bullet point, "In doing so, Dr. Conti's analysis implicitly relies on a uniform noncompensatory decision-rule for calculating damages."

Do you see that?

A. Yes.

Q. So you are saying that she's applying a uniform noncompensatory decision rule, do you not?

A. You forgot a critical word. No, I did not say that, I said she is implicitly applying.

Q. How is that different from her applying, which is my question?

A. The different between an explicit and an implicit application. She does not mention a noncompensatory decision rule, but her assertions are consistent with a noncompensatory decision rule, which is why I said she implicitly applies a

noncompensatory decision rule.
Q. Okay. Thank you for that. That was going to be my next question, is Dr. Conti never uses that term in her report, does she?
A. No.
Q. Thank you.
That's a term -- compensatory decision rules, noncompensatory decision rules, those are terms that are borne out of the field of sort of behavioral science, right? Consumer behavior, consumer psychology, your field of expertise, correct?
A. As I mentioned in my testimony earlier, the foundation for some of this work on compensatory/noncompensatory decision rules came from economists, and I mentioned several, Simon, Tversky, Kahneman, amongst others.
Simon actually was the first one that came up, from what I know, or is at least given credit for the first noncompensatory rule satisfying. This is Herbert Simon, he's an economist.

Q. This is behavioral economics, correct?
A. At that time it was not defined as such, but he's an economist, and now it is commonly adopted in behavioral economics as well.
Q. Let's go to paragraphs 21 through 28 of your report. And this is where you set forth some discussion and definitions of what you mean by compensatory decision rules and noncompensatory decision rules, is that correct?
A. Yes.
Q. For example, in paragraph 22 you state that "The compensatory decision-rule involves physicians and consumers placing a higher value of one drug feature to compensate for a lesser value of another feature," correct?
A. Yes.
Q. There's an assumption there, is there not, that the information regarding those features is available for them to actually weigh, correct?

A. No.
Q. Explain to me how that could not be.
A. Some consumers use their experiences to make judgments about which features are important, what weights they want to put on those features, and how they would evaluate those features even if they did not have any external information.
Q. So what you're saying is that even if -- the consumers may make, you know, make -- draw conclusions without the information, correct?
A. Yes.
Q. Okay. But to actually weigh the benefits, the costs and benefits of a particular feature, that feature has to be disclosed to them, does it not?
A. Explain what you mean by "disclosed."
Q. How can someone weigh the costs and benefits of a particular feature of a medicine, for example, if the feature itself is not known to them?

A. Well, I think you're making an assumption that the feature is not known to them unless someone else gives them the information.
If they have no information on the feature regardless of the source, I agree with you, then they would probably not include it in their decision-making and their valuation. But they can get information from a variety of sources and decide which source they want to include, which source they don't want to include, and make the deliberation accordingly.
Q. There's also an assumption here in this paragraph 22 that the drug, like the hypothetical drug you discuss here, you say, "placing a higher value of one drug feature to compensate for a lesser value of another feature," right? So you're discussing this in the context of a pharmaceutical drug product, correct?
A. I don't believe a chewable multivitamin is a pharmaceutical drug product, but maybe it is.

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Q. Well, I'm not asking about chewable multivitamins. I'm asking about the first sentence of paragraph 22, "The compensatory decision-rule involves physicians and consumers placing a higher value of one drug feature to compensate for a lesser value of another feature."

Do you see that?

A. Yes.

Q. Okay. And by "drug" there you mean a prescription drug, because you're saying physicians as well as consumers, correct?

A. That is incorrect.

Q. Okay. Well, it could include -- when you say "drug," what do you mean there?

A. It could mean any kind of drug, over-the-counter, prescription, any kind of drug.

Q. Okay. So that term "drug" does include prescription drugs?

A. Yes.

Q. Okay. Thank you.

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There's an assumption in there that that drug is actually available to them, correct, for them to be able to engage in some kind of meaningful compensatory decision rule, correct?

A. Incorrect.

Q. How could that be?

A. As a consumer, I could think about, even if I -- something was available but not accessible to me, or not available because it was in short supply, or for some other reason, I could think about what the drug would -- how much value I would place on the drug if it were available, for example.

Q. Okay. But you're not going to end up paying anything for it, correct, because it's not available regardless of what the outcome of the decision is, right?

A. I mean, if there's no product or service, in this case a drug to pay for, I'm not going to pay for nothing.

Q. Right. Exactly.

A. Yes.

Q. Let's take -- are you familiar with the drug Fen-Phen? Do you remember Fen-Phen?

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A. It sounds familiar, but I don't remember any details.

Q. Okay. Fen-Phen was a weight loss drug that was widely used, and then pulled from the market in the late '90s due to severe side effects, so it's not available today.

Do you understand that?

A. I'll take your word for it.

Q. Okay. Can a physician in -- let's say a consumer patient goes in to their doctor today and says, I want you to prescribe me Fen-Phen.

Do you follow me?

A. Yes.

Q. And the drug has been withdrawn from the market, it's not available.

Do you follow me there?

A. Yes.

Q. Okay. What would -- the result of that discussion, no matter how much the patient wanted Fen-Phen, is that the patient is not going to get Fen-Phen, right?

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A. I will say that the physician cannot prescribe Fen-Phen.

Q. Right. And the patient will not be able to lawfully get Fen-Phen, correct?

MR. GOLDBERG: Objection to form.

A. I don't want to make any assumptions here. So, for example, they could go to another country and lawfully get Fen-Phen. I don't want to make an assumption.

BY MR. DAVIS:

Q. Okay. I'm talking -- everything we're talking about today, I'm talking about in the US.

A. Okay.

Q. In the US, a patient really wants Fen-Phen, they go in to their doctor and ask for it, they're not going to be able to get it here because of the way our prescription drug system works, right? You need a prescription from a doctor to get

Fen-Phen, and it needs to be available, approved, and able to be marketed, correct?
A. If Fen-Phen was a prescription drug, yes.
Q. So whatever the decision analysis that the consumer, you know, arrived at based on what they wanted out of Fen-Phen, the serious side effects that ultimately made it unavailable, the outcome of that is going to be they're not going to get Fen-Phen in the US, correct?
A. In your hypothetical example, yes.
Q. Right.
And therefore, they're not going to pay anything for Fen-Phen, correct?
A. Again, there's an assumption there. There are some consumers who would have had to pay nothing even if Fen-Phen was available, so yes.
Q. Okay. Right. They're not going to pay for it, correct?
A. Right. I'm just clarifying that they may not have had to pay for it even

if it were available in some circumstances.
Q. I'll grant you that.
But the outcome is going to be they're not going to pay for it, right?
A. Correct.
Q. You mentioned your multivitamin example, I believe that's in paragraph twenty -- yeah, paragraph 22, sorry, just on the next page, and then spilling over into paragraph 23, right?
A. Right.
Q. Do you know whether multivitamins are subject to the same approval framework as prescription drugs?
A. No.
Q. Okay. Do you know whether any generic multivitamin must demonstrate that it's somehow equivalent to some brand multivitamin in order to be marketed?
A. No.
Q. Another example you provide is Accutane.
Do you recall that?
A. Yes.

Q. Okay. And that appears around paragraphs 38 and 39 of your report, right?
A. Right.
Q. Okay. What's the point you're trying to make with this Accutane example here?
A. The general point I'm trying to make is as a consumer behavior expert, I want to emphasize that consumers have agency, and that they can and do make choices even when they may know about negative side effects to others and even to themselves.
Q. Okay. Those side effects you mention, those are all inherent to the drug itself, correct?
MR. GOLDBERG: Objection to form. Vague and ambiguous.
A. I don't understand.
BY MR. DAVIS:
Q. Sure.
Is there some version of Accutane out there that you're aware of that does not carry those side effects?
A. I cannot speak to that.

Q. You haven't investigated that one way or the other?
A. No.
Q. Can't you deduce that if a generic drug like we've talked about has to show that it's the same as the brand drug in a lot of ways, can't you deduce that Accutane and its generic equivalents out there would all carry the same risk of these various side effects?
A. No.
Q. You can't deduce that?
A. No.
Q. Okay. Do you know whether the FDA label -- have you looked at the FDA label for Accutane?
A. No.
Q. Okay. That's -- do you understand that the FDA label would be exactly where those side effects are disclosed regarding Accutane?
A. I'm not an expert. I'll take your word for it.
Q. Okay. And do you have any

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understanding of whether the generic label for generic Accutane has to read exactly the same way with regard to those side effects as brand Accutane's label?
A. Not an expert. I'll take your word for it.
Q. And you don't understand why the FDA requires that that label be read the same way, do you?
A. Not an expert on the FDA processes. I'm not going to form an opinion.
MR. DAVIS: I'm handing Exhibit 5 to be marked.
(Whereupon, Keller Exhibit Number 5 was marked for identification.)
BY MR. DAVIS:
Q. I'm not going to burden you with reading the entire Accutane label here. Did you -- I guess just answer me this.
Did you, in coming up with your Accutane example in your report, did you look at the label for the drug? I think you said no, right?

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A. No.
MR. GOLDBERG: Objection. Asked and answered.
BY MR. DAVIS:
Q. In your report on paragraph 38 you mention that Accutane "has a number of potentially serious side effects, including: eye irritation; skin infection; bone tenderness; vision loss; birth defects (in pregnant women); skin inflammation."
Do you see that?
A. Yes.
Q. Where did you get that information from?
A. Footnote 62, and it's in Appendix B of my report.
Q. Okay. So that is -- that appears to be the label, so you did --
A. I didn't know that's what the label was. Thank you.
Q. Yes. So this is the label. So you have looked at this?
A. Yes.
Q. And that's how you pulled out

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for example, these potential side effects, was from looking at what's been marked as Exhibit 5, correct?
A. Sorry, can you repeat the question? What has been -- sorry, can you ask the question again?
Q. Sure.
The way you came to understand that Accutane carries the risk of these side effects that you discuss in paragraph 38 is because, as you cite in footnote 62, you actually went and looked at the label for the drug, correct?
A. That's right.
Q. Okay. And that's where those side effects were disclosed?
A. I'm sure -- there may be more, but that's where the ones I've listed were disclosed, yes.
Q. So essentially what happened here is the FDA approved Accutane, correct? The FDA granted approval for Accutane to be marketed to Roche, which was the brand company as you see there.

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Do you understand that?
A. I take your word for it.
Q. And they approved Accutane despite the drug carrying these disclosed side effects, correct?
A. I'll take your word for it.
Q. And left it up to physicians and consumers to weigh the costs and benefits of taking the medicine with those -- with the knowledge of those disclosed side effects in the label, right?
A. Yes.
Q. Okay. Let me ask you, how do you think users of --
A. Should I put this away?
Q. Sure, if you want to.
How do you think users of generic Accutane manufactured by Ranbaxy weighed the fact that that generic Accutane was contaminated?
A. Could you please repeat the question?
Q. Sure.
Are you familiar with a company

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called Ranbaxy?
A. No.
Q. Okay. Let me mark something else for you.
MR. DAVIS: I'm handing Exhibit 6 to the reporter to be marked.
(Whereupon, Keller Exhibit Number 6 was marked for identification.)
BY MR. DAVIS:
Q. Okay. I'm handing you a -- Exhibit 6, for the record, is a US Department of Justice press release titled "Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA."
Do you see that?
A. I see it.
Q. That's dated May 13, 2013?
A. I see.
Q. Okay. So, in fact, if you -- just to orient you, if you go back to

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Exhibit 5 just for a moment, which is the Roche label for Accutane, do you see what the generic name for that drug is?
A. Exhibit -- where? It's a big document.
Q. Well, actually it's in your report at paragraph 38, "As an example, Accutane, or isotretinoin."
A. Yes.
Q. Do you know that Accutane's generic name is isotretinoin?
A. Yes.
Q. Okay. I'm going to direct your attention to page 2 of Exhibit 6, which is this DOJ announcement.
A. Okay.
Q. And you'll see in the second paragraph on that page, "Ranbaxy USA admitted to introducing into interstate commerce certain batches of adulterated drugs that were produced at Paonta Sahib in 2005 and '6, including Sotret, gabapentin, and ciprofloxacin."
And then it says, "Sotret is

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Ranbaxy's branded generic form of isotretinoin," which is Accutane, correct?
A. Is the generic form.
Q. Right.
A. Yes.
Q. So do you see there that Ranbaxy admitted that in 2005 and '6 that they distributed adulterated isotretinoin?
A. According to this statement, yes.
Q. Okay. So my question is, how do you think consumers of Ranbaxy's Sotret or isotretinoin manufactured by them who got that drug in 2005 and 2006 were able to weigh at the moment they went to the pharmacy and got it the fact that it was adulterated?
MR. GOLDBERG: Objection to form.
I think it would be fair to allow the witness to review the document, given the question.
BY MR. DAVIS:
Q. You don't need to review the document to answer the question. I'm asking

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you what I think is a pretty simple question.
How do you think consumers of Ranbaxy's Sotret, which is, as we've seen, generic Accutane, how do you think those consumers in 2005 and '6 were able to weigh the fact that it was adulterated when it was dispensed to them at the time they purchased the drug?
MR. GOLDBERG: I'm going to place the same objection. I think the witness can read the document, that statement that you're asking her about into context. You're sort of showing her a document --
MR. DAVIS: This is filibustering.
MR. GOLDBERG: It is not.
BY MR. DAVIS:
Q. Feel free, Dr. Keller, if you want --
MR. GOLDBERG: You placed a document in front of the witness, you didn't give her a chance to review it. Let her review the document, and let

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her answer the question.
BY MR. DAVIS:
Q. I'm not sure how helping the document is going -- or reviewing the document is going to help you answer the question. I've set forth a fact that was admitted to by Ranbaxy, which is that they distributed in 2005 and 2006 certain adulterated batches of isotretinoin.
You see that in the document, do you not?
A. Yes.
Q. Okay. And you have no reason to dispute what Ranbaxy is admitting there, correct, that they did that?
A. Right.
Q. Okay. So my question to you is, how do you think consumers who purchased those adulterated isotretinoin prescriptions in 2005 and 2006 were able to weigh the fact that they were adulterated in 2005 and '6 when they actually bought the drugs?
A. This is the reason for wanting to read the document, to see if there is any

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context that would help me answer the question more accurately.
Q. The fact is they couldn't, right? The answer is no, they can't weigh that information, right, because they didn't know it, right?
MR. GOLDBERG: Objection to form.
A. Again, I don't know that. I accepted what you said earlier when you pointed to where I -- where that was in the report. If you let me read this report, I'll see if that same statement is made in the report, and then you can ask me the question again whether I have any reason to doubt it.
BY MR. DAVIS:
Q. Okay. Take a few moments.
MR. DAVIS: Let's go off the record.
MR. GOLDBERG: No, let's not go off the record. The document is a couple of pages. Under the rules in this case, the witness gets to read the document for a few minutes, if

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it's going to take longer we'll go off the record. But we don't go off the record automatically just because a document is presented. That's how it goes.
BY MR. DAVIS:
Q. Feel free to give the document a cursory review.
A. I'm sorry, I'm going to undertake my task so that I can answer your question to the best of my ability.
Q. Sure. Okay.
A. Thank you.
Q. Review the document.
A. Thank you.
(Witness reviewing document.)
A. Thank you.
Q. Sure. So let's start with the portion of the document that I called out to you.
You agree that Ranbaxy admitted to distributing in 2005 and 2006 certain batches of adulterated isotretinoin, which is generic Accutane, correct?

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A. Yes.
Q. Okay. So my question is, how can consumers who purchased those drugs in 2005 and '6 have weighed the fact that they were adulterated at the time that they purchased them?
A. You are making an assumption that consumers uniformly would have wanted to weigh that fact.
Q. No, that's not my question, and you're not answering my question.
My question is, how could they have weighed that information when it wasn't disclosed to them?
A. But the assumption is that they would even want to. So if I don't want to, the issue of how I could is irrelevant.
Q. Well, you're taking it -- you're taking my question and you're answering a different question.
A. I see.
Q. My question is, how can consumers who purchased adulterated Ranbaxy isotretinoin in 2005 and 2006 that was

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adulterated, how could they have weighed the fact that it was adulterated? If they wanted to weigh that fact, how could they have weighed that fact that it was adulterated? They couldn't, right?

A. Again, I'll explain why I'm having a hard time answering that question directly.

Based on my understanding of consumer behavior, there are consumers who think drugs are adulterated when they're not and consider that. And the example that I give in my report was on -- because we were talking about COVID vaccine earlier, about bleach, and I cited a supporting document, you know, something from the CDC on the percentage of people that were using bleach because they thought that was more efficacious for them or safer or whatever set of reasons they had that I'm unsure of than the COVID-19 vaccine.

So I don't -- I said this earlier, I don't think that consumers need to get specific information in order for them to

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include features, whether they're benefits or costs or both in some cases, in order to make a determination of how they impact the value that they are assessing.

Q. You don't think consumers are entitled -- you don't think these Ranbaxy isotretinoin consumers were entitled to know that the drug they got was adulterated? Is that what you're saying?

A. No, I did not say that. I actually don't know what you mean by "entitled."

Q. You don't think it would have been right for them to know that the drug they were getting was adulterated?

A. There are some consumers who would say, It is my right to know, and there are others who would say, I don't care.

There is a range of consumer behavior, and I don't think that you can uniformly assume any consumer would be exactly the same in this context of they would feel that they have the right to know.

Q. But you're not answering my

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question. You're answering a different question, which is how they might have weighed that information or not have weighed that information.

My question is, it wasn't disclosed to them, so even if they wanted to weigh it they couldn't have, right? Even if they would have considered that in their decision-making, they couldn't have, right, because it wasn't disclosed to them. Would you agree with that?

A. So you're saying make the assumption that people -- that there were people who wanted to know, and then -- you're asking me to make a lot of assumptions.

Q. Well, I don't think it's a big assumption to assume that people would want to know that their drug was contaminated.

A. Some will and some will not, and that's what I said.

Q. Assume it for me, Dr. Keller, assume that there were patients of Ranbaxy's Sotret who would have wanted to know that information.

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A. Okay.

Q. But they didn't know that information at the time they purchased the drug, right?

A. Correct.

Q. Okay. How could they have weighed that information when it wasn't disclosed to them? They couldn't have, right? They could not have weighed that information, correct?

A. They could not have weighed the specific information, but they could have weighed related information.

Q. What do you mean by "related information"?

A. You know, there are consumers out there who believe that pure drugs is an oxymoron, and that -- you know, and as I state in my report in Section IV, I think it was IV.B, which is what we were referring to earlier, there are some consumers who learn over time that things that they thought were safe were not safe, and things that they thought may have not been safe have reentered

the market in a different form or in some other form.

So I think the situation is much more fluid, and that consumers are aware of this.

Q. So you're saying that you don't think consumers should be entitled to expect that the drugs that are distributed to them at the pharmacy are as approved by the FDA?

A. I would never use consumers, if your -- I would never agree to any sentence that says "consumers" if by that you mean all consumers.

Q. I'm asking, because you said that -- I think you said that the notion of a pure drug was an oxymoron. Is that what you said?

A. I said for some consumers, not for -- remember, I'm doing -- I'm applying the same rule to myself that I'm applying to you. I said for some consumers. I would not say for all consumer a pure drug is an oxymoron.

Q. So what you're saying is you

don't think consumers of pharmaceuticals dispensed in the US should be entitled to a belief or an expectation that those drugs are dispensed to them as described and approved by the FDA?

A. Again, I don't believe that is the case for all consumers. I think many consumers don't think about whether the drug is approved or not approved, or who approves it or doesn't approve it.

And I'm going to break one of my own rules and give you an example where if I was taking a drug, and it could be this one that you have as an example, and I thought it was working brilliantly for me, I might not want to know that the drug -- I mean, sorry, I can say drug, yeah -- that the drug was adulterated because I would like to continue taking the drug without any trepidation.

Q. You might not want to know?

A. I might not want to know.

Q. Well, what if -- I mean, we're talking about just one manufacturer's version of generic Accutane, you wouldn't want to

know that so you could just take another manufacturer's version of generic Accutane that wasn't adulterated?

A. It's a hypothetical, so I'm giving you a hypothetical back, and that is, if I like this one that I'm taking and it's worked for me -- and back to my framework that I talk about in the model, and I'll use MICI this time, which is, depending on the message that I got -- and I can give you examples, depending on -- I'm focusing on the individual differences, that if I've tried other acne medicines and they haven't worked for me, and then I find one that I really like and it seems to work for me, and then there is this information out there, I'm saying that there are some consumers in those situations that might not want to know or not care about this information about the adulteration from this specific batch because they don't want to switch, they don't want to consider any alternative products.

Q. Do you understand that the point of our generic drug system is that all

the generics are supposed to work in the same way to each other and to the brand?

MR. GOLDBERG: Objection.

BY MR. DAVIS:

Q. Do you understand that?

MR. GOLDBERG: Objection to form. Asked and answered.

A. I am not an expert on how generics are supposed to work, and I will not give you an opinion on that.

BY MR. DAVIS:

Q. Let's back up for a second.

You talk a lot about this choice exercise that consumers make in the healthcare context, right?

A. Which context are you speaking? We were talking about how a consumer might value the drug that they have, so when you say "choice exercise," I'm trying to understand the context.

Q. Sure.

Your whole report is about healthcare decision-making, right? And that involves a choice, right?

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A. I would say that that's a bit of a mischaracterization. The bulk of my report is focused on how consumers would assess the value or worth of a drug to them.
Q. Okay. And once they make that assessment, at what point is the decision finalized for them?
A. Lots of cases, never. In some cases, they try one, they never switch. That varies by consumer.
Q. Well, the choice is culminated when they go buy the drug, right? They're acting, would you agree --
A. No, no.
Q. Would you agree that a consumer, when they go fill a prescription, they're acting on a choice that they've made, correct? They may -- I hear what you're saying, they may reevaluate that choice in the future, but they're acting on a choice that they made prior to that, because they had to -- I mean, it's just common sense, you go fill a prescription, you're doing an act, right?

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A. As I mentioned to you earlier, the consumer value is defined as a comparison of benefits and costs, and the price they pay or the act of actually exchanging a product for money is only one aspect of the cost.
Q. It's an action, though, that a consumer is taking, correct?
A. It's one of several.
Q. As a result of the decision and choice analysis that they went through prior to engaging in that act, right?
A. I take objection to that. As I explain in my report, and this is in Section IV.B of my report, consumers use a variety of different methods to make those choices. Some of them are noncompensatory or reflexive, they haven't thought about anything, they've just gone and done it spontaneous, others -- there's a range -- others will spend a lot of time and think about the plusses and minuses. There's a range.
Q. I'm not going into the qualitative aspect of that choice. All I'm saying is that in order to act, which is to go fill the prescription at the pharmacy, some level of choice had to be made to go do that. We're not talking about zombies here who are just like, you know, going to the pharmacy, this is a choice that humans make to go fill a prescription, is it not?

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A. I would say some will go fill and some will not. And again, as is explained in my report, many consumers do not fill their prescriptions, and many consumers who fill their prescriptions do not take their drugs. So those are also actions.
Q. So with this Sotret example, which consumers affirmatively made the choice to go get adulterated Sotret from Ranbaxy?
A. I have no idea.
Q. None, right?
A. Well, no, that is -- I have no information on that. I can't tell you that.
Q. If you don't know -- if they didn't know about it, how could they affirmatively go choose that at the time? They can't, right?

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A. I'm going to repose -- I'm going to, sorry, reframe, reframe that question.
Compare that to a consumer who should have had the information, could have had the information but did not, right? What is the difference between their action and someone who could not have known?
Q. Do you have any -- is there any indication in this DOJ announcement that you read that any consumer had any indication, or any ability to even go and find out that Ranbaxy's Sotret was adulterated at the time it was dispensed to them?
A. That information is not contained in this document.
Q. In fact, the opposite is contained in the document, right? Part of the settlement was related to Ranbaxy knowing and not telling the FDA until 2007, which is years after the adulterated Sotret was distributed in 2005 and '6, right? So the indication in this document at least is that no one knew except Ranbaxy, right?

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A. I don't know that to be a fact.
Q. Okay. Take a look at the last paragraph of page 3 of this document. It says -- and this is a quote from John Roth, the director of the FDA's office of criminal investigations. He says, "The FDA expects that companies will comply with the cGMP requirements mandated bylaw so that consumers can be assured that their medical products are safe and pure."
Do you see that?
A. Yes.
Q. Okay. Is there anything about that statement that you disagree with?
A. I am not an expert on the FDA, so I have no idea what they expect companies to do.
Q. Do you think that consumers are entitled to the same expectation that the FDA has here, which is that their medical products are safe and pure?
A. Again, it depends on how you ask consumers those questions. If they had to make trade-offs, they might make different

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trade-offs on how important safety or purity might be to them if it meant lower efficacy or lower experience for them.
Q. So you're saying that consumers of prescription drugs in the US should be forced into a position of making a trade-off that includes whether their products are safe or pure?
A. That is not what I said.
Q. Wouldn't that position completely undermine our prescription drug approval framework in this country?
A. I am not an expert on the approval drug process, and I am not offering an opinion on it.
Q. Okay. Go back to page 1 of this document, which is Exhibit 6 for the record. Another quote from Stuart Delery, who was acting assistant attorney general for the civil division of the department -- U.S. Department of Justice. He says, "When companies sell adulterated drugs, they undermine the integrity of the FDA's approval process and may cause patients to take drugs

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that are substandard, ineffective, or unsafe."
Do you see that?
A. Yes.
Q. Okay. Do you agree from a -- put your marketing consumer-patient messaging hat on -- do you agree that that would complicate your job if the integrity of the FDA's approval process was undermined?
A. I cannot answer that question.
Q. Okay. You don't think it would be harder, for example, to advocate for medication compliance when -- if the approval process for that very medication was -- the integrity of it was undermined because companies were selling adulterated drugs?
MR. GOLDBERG: Objection to form. Ambiguous.
A. I cannot answer that question.
BY MR. DAVIS:
Q. On page 3, back to page 3 of Exhibit 6, you'll see a paragraph, second to last paragraph, "Last year" -- which would have been 2012 based on the date of this

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document -- "FDA and Ranbaxy agreed to an injunction that prevents drugs produced at the Paonta Sahib and Dewas facilities from entering the US market until the facilities have been brought into full compliance with the FDCA and its implementing regulations."
Do you see that?
A. Yes.
Q. So for that period of time from the beginning of the injunction until a determination of full compliance was made, there was no consumer in the US market who could have gotten a Ranbaxy drug produced at those two facilities, right? Is that what that says?
A. I will make that assumption that there were no leftovers or -- there's many assumptions there, but okay.
Q. And so, therefore, there would have been no supply of drugs from those facilities, correct, entering the US market?
MR. GOLDBERG: Objection to form.
A. Please explain that.

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BY MR. DAVIS:
Q. I'm not sure what there is to explain.
There would have been no supply of drugs from those two facilities that could have entered the US market for the period of the injunction, correct?
MR. GOLDBERG: Objection to form. Foundation.
A. So can you please explain what period we're talking about?
BY MR. DAVIS:
Q. Sure.
The period that I thought we had understood, which was the beginning of the injunction until full compliance.
A. So I'm not a lawyer, and, you know, I need to understand. You know, these are fluent terms for you.
So when you say "the beginning of the injunction," what -- and you're asking me about a time period, so what time period am I referring to?
Q. The date of the injunction last

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year, so 2012, FDA and Ranbaxy agreed to an injunction.
A. So from 2012 to?
Q. Whatever that date was that they were brought into full compliance, if that date ever occurred, would you agree with me that there was no supply of Ranbaxy drugs from those two facilities that could have entered the US market?
A. I am not an expert on this and I cannot answer that question.
Q. I mean, it just plainly says it there, doesn't it?
MR. GOLDBERG: Objection to form. Argumentative.
A. It's not plain to me.
BY MR. DAVIS:
Q. So the FDA and Ranbaxy agreeing to an injunction that, quote, prevents drugs produced at the two facilities from entering the US market, that doesn't suggest to you that, for that time period, that there was no supply of Ranbaxy drugs into the US market from those two facilities?

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A. I will repeat why I am not saying that there was no supply. In part, I don't know what supply there already was in the marketplace, I don't know what -- how it was recalled, I don't know what instructions people gave, physicians and otherwise, as to what people should do with whatever supply was available, and I actually from this sentence don't even know.
It says earlier that they're going to work with them. I don't know when they started working with them and allowed them to reenter the market. I don't know.
Q. Do you know what happens to the supply of pharmaceuticals that are already in the market once a recall is announced? Do you know what happens to those pills that are sitting on warehouse shelves or pharmacy shelves after the recall is announced?
A. I am not an expert on this, and I will not form an opinion.
MR. GOLDBERG: John, I think we've been going about 90 minutes.
MR. DAVIS: Sure. Five

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minutes?
We can go off the record.
MR. GOLDBERG: Yes, let's go off the record.
THE VIDEOGRAPHER: Off the record at 1:53.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: Back on the record at 2:09.
BY MR. DAVIS:
Q. Okay. Dr. Keller, we left off, I was asking you about this FDA Ranbaxy injunction, I was asking you how that would have affected the supply of Ranbaxy's in this case Sotret that we were talking about into the market that was produced at these two facilities, into the US market.
Do you recall that discussion?
A. I recall the discussion before the break, yes.
Q. Okay.
A. Should I bring this document forth again?

Q. No, I was resetting our --
A. I'm sorry. Okay.
Q. -- context here.
Have you examined in any detail how the fact of adulteration in this case, for example, affects a company's ability to supply their drugs into the US?
A. I need a clarification.
Q. Sure.
A. In this case are we talking about the Ranbaxy case, or are we talking about the VCD case, or some other case?
Q. I'm just talking generally about pharmaceutical prescription drugs.
A. Okay.
Q. Did you as part of this assignment, or not as part of this assignment, just generally, have you ever studied how the fact of a prescription drug's adulteration affects its ability to be distributed, marketed, sold, dispensed in the United States?
MR. GOLDBERG: Objection. Ambiguous and compound.

A. I am not an expert on many of the things that were raised, and I'm not going to give an opinion.
BY MR. DAVIS:
Q. So you haven't looked into how the fact of adulteration might affect the supply of a drug in the US?
A. Not prior to this case.
Q. Did you in this case?
A. I reviewed Dr. Conti's report, so yes.
Q. Okay. I'm asking not did you review Dr. Conti's report. I'm asking if you did any independent analysis of your own how the fact of adulteration under the law might affect the supply or the ability of a manufacturer to supply its drug product in the United States market?
A. No. I am a consumer behavior expert. I have no opinion on drug supply for the example you've given.
MR. DAVIS: I'm going to mark Exhibit 7.
///

(Whereupon, Keller Exhibit Number 7 was marked for identification.)
BY MR. DAVIS:
Q. I understand you're not a lawyer, Dr. Keller. What I'm showing --
MS. ANDRAS: Can you please identify it with specificity on the record?
MR. DAVIS: Sure. For the record, this is Exhibit 7, which is 21 USC 331, part of the US Code entitled "Prohibited Acts."
BY MR. DAVIS:
Q. Do you see that?
A. Yes.
Q. Do you have familiarity with what the US Code is?
A. No.
Q. Do you understand that that's federal law enacted by congress, signed by the President?
MR. GOLDBERG: Objection to form. Foundation.

A. I did not know that. I'm not an expert on the law.
BY MR. DAVIS:
Q. Okay. I'm granting you that.
It says there that, "The following acts and the causing thereof are prohibited." And then it says, "(a) The introduction or delivery" into -- sorry. "The introduction or delivery for introduction into interstate commerce of any," and it lists several things, including drugs, that are adulterated or misbranded.
Do you see that?
A. Yes.
Q. Okay. And then (c) says, "The receipt in interstate commerce of any" of the same categories, including drugs, that are adulterated or misbranded, and the delivery or preferred delivery thereof for pay or otherwise.
Do you see that?
A. I do.
Q. Okay. Were you aware -- your testimony is you're not aware of these

prohibitions under federal law, are you?
A. Correct.
Q. Okay. Thank you.
MR. GOLDBERG: Are you done with this one?
MR. DAVIS: For the moment, yes.
BY MR. DAVIS:
Q. Do you have any opinion about, or -- let me rephrase it.
Do you have any understanding about whether the at-issue VCDs in this case were deemed to be adulterated or misbranded under the law?
A. I don't have an opinion.
Q. Okay. You don't have any understanding, correct?
A. That's not what you asked. You asked if I had an opinion. So could you reask the question?
Q. Sure.
MR. HONIK: I'd like Maureen to read it exactly as John posed.
THE WITNESS: Thank you.

(Whereupon, the reporter read back the question:
QUESTION: Do you have any understanding about whether the at-issue VCDs in this case were deemed to be adulterated or misbranded under the law?)
MR. HONIK: Not opinion.
A. I apologize.
Could you read that again?
(Whereupon, the reporter read back the question:
QUESTION: Do you have any understanding about whether the at-issue VCDs in this case were deemed to be adulterated or misbranded under the law?)
A. I am not a lawyer. I do not -- I am not going to offer any opinion on that.
BY MR. DAVIS:
Q. Okay. And the question was, you don't have any understanding of whether they were or not, correct?
A. Please explain what you mean by

"understanding."
Q. So my question was, do you have any understanding of whether the at-issue VCDs in this case were deemed to be adulterated or misbranded under the law?
A. I will answer to the best of my ability. I have read the -- as you can see in Appendix B of my report, I have read a couple of legal documents that explain that some of the at-issue VCDs were found to be adulterated and unbranded under the law.
Q. Okay. But you're not sure how many, right? You said "some." You're not sure whether it's some or all of them, are you?
A. I am -- my understanding, which is what you asked, is that of the VCDs that were voluntarily recalled by the manufacturers, some of them, not all of them, were adulterated or unbranded.
Q. You're not sure how many that is, though?
A. No.
Q. Okay. And you didn't do any

independent analysis of whether that's true or not true, right?
A. Correct.
Q. Okay. Do you have any understanding of whether there are valsartan-containing drugs out there that don't have and never had NDMA and NDEA in them?
A. I am not an expert. I will qualify that some of the material that I have in my supporting documents suggested -- indicated to me that there were levels of these two impurities that you just mentioned, but I am assuming they were acceptable levels.
Q. So my -- that's not my question, though. My question -- and I'll reask it just to make sure we're clear, my question is, do you have any understanding of whether there were not at-issue VCDs manufactured by entities other than the defendants in this case that did not have any NDEA or NDMA in them?
A. I have no information on them.

Q. You have no information on that.
Didn't look at it?
A. No.
Q. Didn't investigate it?
A. No. Not part of my task.
Q. Do you have any understanding of whether NDMA or NDEA are supposed to be in valsartan drugs?
A. I'm not an expert on the formulation of these drugs. I have no opinion.
Q. Okay. So you don't know whether these two substances are supposed to or not supposed to be in valsartan drugs?
A. I am not an expert. I cannot comment as to the presence, absence, or extent to which these are or are not necessary for these drugs.
Q. Well, the drugs were recalled, as you said, right?
A. (Nodding in the affirmative).
Q. Doesn't that indicate to you that they weren't supposed to be in there?

A. My caveat is when you say they're not supposed to be there, my understanding is that they are there, it's just not they're not supposed to be there above certain levels, and that's what I'm qualifying.
Q. But you don't know whether they're supposed to be there at all or not, correct?
MR. GOLDBERG: Objection to form. Foundation.
A. No.
BY MR. DAVIS:
Q. Did you look at a valsartan label like you looked at the Accutane label?
A. I already testified that I looked at valsartan product labels.
Q. Can you point me -- it may be in there, I just want you to point me to where in your materials considered that would be.
A. I can show you from my report, but I don't have the binder of all the -- and actually there's maybe six on a page, they're

visuals, in case you have those materials and you're trying to look for them, but I can help.
(Witness reviewing document.)
A. I'm -- I wish I had my materials in front of me, but I'm going to -- I don't want to guess. It could be in the drugs.com or the MedlinePlus. I'm picturing the page in front of me, and they're pictures of multiple labels with on the left side the name, and on the right side the drug manufacturer and the place of manufacture. That's what I'm picturing.
Q. Okay. You say -- flip to page 30 of your report, if you don't mind, Exhibit 1.
A. Of course.
Q. The title of that section is "Real-world Evidence Indicates that the At-Issue VCDs Held Value," correct?
A. Yes.
Q. Okay. Did you look at any sales data of -- sorry.
Did you look at any sales data

of the actual sales of these drugs after the recalls were announced?
A. Only information that was part of Dr. Conti's report, not otherwise.
Q. So do you know what happened to sales of these products after the recalls?
A. I don't recall.
Q. Sorry, give me a few moments here. I should have two copies of all this somewhere, but I don't. I'm just going to mark one, it's big enough for, I think, you to see it.
MR. DAVIS: This is being marked as Exhibit 8, let's start with that.
(Whereupon, Keller Exhibit Number 8 was marked for identification.)
BY MR. DAVIS:
Q. Let me represent to you that what I'm showing you there is the monthly prescription data for --
A. Should I put the -- my report away?

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Q. Sure, sure.
A. Thank you. Okay.
Q. What I'm representing to you here is that what's marked as Exhibit 8 is a graph showing monthly prescription data for ZHP manufactured valsartan products.
Do you understand what I mean by that?
A. Yes.
Can I ask a clarifying question --
Q. Sure.
A. -- so I know how to interpret this graph?
Q. Yes.
A. I see that the X axis is labeled as time, but the Y axis is not labeled, and so I'm not quite sure how to interpret a graph with only one labeled axis. I could be missing something.
Q. Read for me, if you don't mind, the header up at the top there.
A. "Monthly ZHP Rxs by Valsartan Product."

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Q. Okay. So what I'll represent to you that the Y axis is there is Rxs, which is prescriptions.
Do you understand that?
A. So these are prescription -- just clarifying, these are prescriptions of valsartan over this period of time.
Q. Correct, manufactured by ZHP.
A. Right. Prescriptions that were given, filled, or -- just again clarifying, because it isn't labeled.
Q. Prescriptions that were filled.
A. Thank you.
Q. Yes. Absolutely.
You didn't look -- I think your testimony was you didn't actually look at any of the sales data, did you?
A. Not unless it was in Dr. Conti's appendices.
Q. Do you see that the sales abruptly dropped to zero?
A. So can I now assume in the Y axis that the bottom is the zero?
Q. Yes, yes.

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A. Okay. Then yes.
MR. GOLDBERG: Objection to form.
BY MR. DAVIS:
Q. Do you understand why for ZHP the monthly sales dropped to zero?
A. I don't have that information.
Q. Did you come to any understanding or investigate whether similar to Ranbaxy, ZHP was barred from importing prescription drug products to the US?
A. I just want to make sure, exporting, that ZHP was barred from -- we barred them from imports of their product, right?
Q. Yes. ZHP products were made illegal to sell in the US, correct?
A. Yes.
MR. GOLDBERG: Objection to form.
BY MR. DAVIS:
Q. And subject to seizure by federal agents if they were imported or attempted to be distributed?

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A. I am not an expert on this process. I cannot form an opinion.
Q. Well, you sort of do form an opinion, though. If you look at paragraph 71 of your report, you have a hypothetical supply-demand curve, do you not?
A. Excuse me, I need to get there.
Could you ask that question again?
Q. Sure.
You said you don't have an opinion one way or the other on whether ZHP was barred from importing or selling its products in the US. Am I right about that?
A. I'm not sure, that may have been before your last question, I don't recall that as your last question, so I'm trying to be accurate.
MR. DAVIS: Could you read that last question? Sorry.
(Whereupon, the reporter read back the following:
QUESTION: And subject to seizure by federal agents if they were

imported or attempted to be distributed?

THE WITNESS: I am not an expert on this process. I cannot form an opinion.

QUESTION: Well, you sort of do form an opinion, though. If you look at paragraph 71 of your report, you have a hypothetical supply-demand curve, do you not.

THE WITNESS: Excuse me, I need to get there.

Could you ask that question again?

QUESTION: Sure.

You said you don't have an opinion one way or the other on whether ZHP was barred from importing or selling its products in the US. Am I right about that?)

BY MR. DAVIS:

Q. So let me -- I'll withdraw the last question.

You do at paragraph 71 on

page 43, the next page over, supply a hypothetical supply-demand curve, do you not?

A. Several.

Q. Well --

A. Several demand curves, and therefore --

Q. You have several demand curves, but you have one supply, correct?

A. Yes, so a combination would be several supply-demand curves.

Q. Right. But with one supply line, correct?

A. Yes.

Q. And this is hypothetical, right? This is a hypothetical supply-demand curve, is it not?

A. Well, it is a figure, and the changes or the alternatives of the demand curve that I'm sharing with you here reflect my argument that consumers would have different assessments of what the drug would be -- what the at-issue VCD would be to them, and based on the compensatory/noncompensatory decision rules and MICI.

And some consumers would say, I don't want any of this product, it is not worth anything to me, all the way to the other end of the continuum where you have some consumers who would say, I'm consuming these impurities in multiple forms and it's of no consequence to me, and everything in between.

That's what these alternative demand curves, or multiple demand curves are meant to represent.

So when you ask the question, you know, are they hypothetical demand curves, yes, they are, as that they're not based on data, nor is the supply curve, by the way, based on data, they're just representing how my frameworks and opinions would translate into alternative demand curves.

Q. Okay. And that was -- I think you've answered my next question, which is, this is not informed by any look at data, is it? These are hypothetical scenarios you're putting forward, right?

A. Yes.

Q. And in fact, your supply curve is just inconsistent with the facts if you accept, for example, the ZHP graph as actually representing the sales situation, correct?

A. It is incorrect, because the example that I'm giving you in my report is that one can retrospectively go to those consumers -- because there was supply, they were supplied the product. I mean, I'm not a lawyer, but how do you have a recall if there's -- no product was given? How do you make, what, ZHP or any manufacturer say they committed fraud because they sold something if they didn't sell anything. So if there's no supply, how is it possible if someone sells something that there's no supply.

So I'm just saying that this to me is not relevant -- sorry, your -- what exhibit is this?

Q. This is Exhibit 8.

A. Sorry. Oh, I see that.

Exhibit 8 does not help inform

my figure on page 43, because they were supplied. And I'm saying that if you went back retrospectively and asked those consumers, Hey, given what you know now about the impurities and whichever way you want to define it -- and that is going to make a difference how you define it and how you communicate it and who communicates it -- how would you assess the value of the work of this -- of the at-issue VCD that you took.

And all this is saying here in my figure is that you will get a range of responses.

Q. What literature do you have to support what appears to be your proposition that an economic damages analysis should be based on a retrospective look as opposed to measuring at the time of injury?

A. I am not a lawyer. I don't have an opinion on that.

Q. Okay. And you're not offering an economic damages analysis here, are you?

A. No.

Q. And you're not qualified to do

that, correct?

MR. GOLDBERG: Objection to form.

A. It was not my task. I did not do that.

BY MR. DAVIS:

Q. So -- and we'll get to the retrospective aspect of this later.

A. Should I put it away?

Q. Sure.

But my question is, after the point of recall, there was no supply of ZHP valsartan in the US, was there?

MR. GOLDBERG: Objection to form. Foundation.

A. No. According to this graph, based on how you described it to me, no more prescriptions were filled for this product after this period on the X axis.

BY MR. DAVIS:

Q. Correct. That means there was no more supply of it, correct, in the US market?

MR. GOLDBERG: Same objection.

A. That is incorrect.

BY MR. DAVIS:

Q. How is that incorrect?

A. Because the information in this case, and some of it is described in Section IV.E of my report, that not only was there evidence that consumers continued to take the recalled valsartan based on depositions from plaintiffs, but that -- and I've quoted some of them, but that physicians, and I've also quoted some of them, encouraged some of their patients to continue taking the recalled valsartan until they had other options.

That is my understanding of why there had to be supply if that was -- if the information I just shared is true.

Q. That's existing supply, right, what had been distributed, dispensed to patients prior to the recall, correct?

My question is, after the point of recall, are you aware of any evidence of a single prescription of ZHP valsartan being dispensed to a patient after the point of recall?

A. I don't have that information.

Q. Okay. So your supply curve here that you supply is just inconsistent with the facts, correct?

A. No.

MR. GOLDBERG: Objection to form. Argumentative.

A. And I'm assuming now you're referring to my report, because we have multiple supply curves here.

BY MR. DAVIS:

Q. I'm talking about your hypothetical supply curve, not what the actual data show.

A. Got it.

So could you please repeat the question?

Q. Your hypothetical supply curve here is uninformed by the facts of this case, is it not?

A. This figure is -- and you can look at the context before and after, and I will read it out to you because it's on the same page, 72, "As shown in the figure above,

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there existed some original supply and demand curve (denoted by 'Demand0' and 'Supply'), which resulted in an equilibrium price, P0, and equilibrium quantity, Q*. Instead of removing the supply curve, and assuming zero demand, it is more appropriate to envision how each consumer's demand would shift due to knowledge of the presence (or potential presence) of impurities."

Q. Let me ask you about that.

You say that there would be an equilibrium price, you just read me that, right?

A. That's one. There are multiple equilibrium prices based on which demand curve you're referring to.

Q. Let me ask you a very specific question, which is, after the point of recall for ZHP, since you have that data right in front of you, after the point of recall there would have been no supply -- there would have been no equilibrium price because there was no supply, right?

A. Yes and no.

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Q. Okay. Well, how is it different from what you -- do you recall our discussion of Fen-Phen earlier?

A. Yes.

Q. And you agreed with me that even if a patient wanted to get Fen-Phen they couldn't get it, they couldn't pay for it, right? How is it different after the point of recall for ZHP valsartan?

A. Let's use your Fen-Phen example. What I'm trying to communicate here is how consumers make decisions about what a product is worth to them, and price is one manifestation or reflection of that. It is not the only one. Let me just finish.

Your Fen-Phen example, you brought it up again, the way -- from my recall of how you described the situation is it was recalled, and if a consumer of Fen-Phen went to their physician and asked for Fen-Phen, they could not write a prescription for Fen-Phen. Am I right? Is that a good --

Q. Yes.

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A. The very fact that consumers are going and asking their physician for Fen-Phen -- I'm not making any assumptions about all consumers here, you know that -- and there's a possibility that they knew about the recall, and I'm going to go one step further and say given my knowledge of consumer-physicians' interactions, they might have even asked the physician why it was recalled, they still wanted it.

So that gives you some sense of how consumers will calculate what is valuable to them or what is worth to them, even if in your example the product is not available.

Q. So, but my question is different. My question is, there is no equilibrium price. Let's say there was some crazy consumer who said, Yes, I want the carcinogen-laced valsartan, and went in and asked their physician for that, the physician couldn't give them ZHP valsartan, could he?

MR. GOLDBERG: Objection to form. Argumentative.

A. Well, first I want to say, and

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I'm relying on my frameworks, depending on how that message was communicated, if you say carcinogen-laced the way you said it versus a valsartan that may contain impurities, the individual's -- I'm using MICI factors -- the individual's status, so if they were happy with their valsartan and had -- as I shared in my report in Section IV.E, they were happy with their valsartan, they had serious health issues, they may have even tried alternative medications and felt that the valsartan was the best at controlling their hypertension, and contextual factors, how much their relationship with their doctor and their ability or inability to have a healthy lifestyle, all of those factors would have an impact on what they thought the drug was worth.

BY MR. DAVIS:

Q. Okay. But you're not answering my question.

My question is, if there's no supply after the recall, as you can see from the sales data, even if a consumer -- like

let's just assume that there is a consumer who does want ZHP valsartan after the recall and wants to go get a new prescription of it from their doctor, the result is just like it was with Fen-Phen, they can't get it, right?

A. I'm assuming that is the case, yes.

Q. And they would end up, therefore, paying no money for it, correct?

A. Yes.

Q. Okay. Thank you.

And there would be no intersection of -- sorry, showing you my screen, you've got it right there.

A. Yes.

Q. There would be no intersection of supply and demand in that very specific situation I just asked you about, correct?

A. Correct.

Q. Okay. Thank you.

A. Should I put these away?

Q. Sure.

A. Okay.

MR. DAVIS: I'm marking

Exhibit 9.

(Whereupon, Keller Exhibit Number 9 was marked for identification.)

BY MR. DAVIS:

Q. This is a -- can you identify this document for me?

A. No.

Q. I'll represent to you that it's a valsartan -- I'll represent to you that it's a valsartan label, which may or may not -- I think, we looked at your materials considered.

Is this a document you recall seeing ever?

A. No.

Q. Okay. I'll represent to you -- but, you know, you're free to look, but I'll represent to you that there's no mention of nitrosamines, NDMA, NDEA, anywhere in this label.

Are you willing to accept that, or do you want to take a look?

A. I actually don't have any idea

what is in this label period, so I don't know how to understand the absence of the two impurities you just mentioned.

Q. Well, I'm not asking you yet to understand the absence of them. I'm just asking you if you see any reference to them in that document.

A. I cannot do that. You're asking if there's any reference, and I don't know if there's any reference without having a chance to review the document.

Q. Okay. So you're not willing to take my word for it that they're not in there? You're willing to look. Why don't you take a look, that's fine.

Do you want to look at -- and I can direct your attention, for example, to make this go a little faster, okay, if you don't mind, go to the very last page.

Do you see that last question there, "What are the ingredients in Diovan?"

A. I do.

Q. Okay. Do you see any reference to NDEA, NDMA?

A. I am not a chemist. I don't know the different forms and labels. Those drugs may be represented some other way. I cannot answer the question.

Q. Would you agree with me -- let's start with just a very general proposition.

Would you agree with me that a manufacturer of valsartan when they distribute it into the US market, by calling it valsartan and by distributing this label with it, they're conveying some kind of message to the people that will interact with it, namely physicians and consumers, correct?

MR. GOLDBERG: Objection to form. Foundation.

A. Please be more specific.

BY MR. DAVIS:

Q. Do you think that by -- when a manufacturer of valsartan distributes valsartan in the US market, by calling it valsartan, are they conveying a message that it's valsartan? It's a pretty general proposition, right?

A. They're saying it's valsartan. I'm not going to speak to what that means to consumers, or physicians or anybody else.
Q. But there's a message embedded in there, right, that this is valsartan, correct?
A. I am not an expert on the drug ingredients, and I don't know what that communication would mean.
All I'm willing to acknowledge is if they say it's valsartan, that that may have meaning, and different meanings to different people. I am not an expert on valsartan, and I cannot give you an opinion.
Q. Sure.
And let's excise that from the question, which by that I mean whatever valsartan means, by calling it valsartan, the manufacturer is conveying a message that it's valsartan, whatever that means, right?
A. I'm just -- I am always representing the consumer point of view, and valsartan would just have different meanings for different consumers based on the

different messages and the context in which these, you know, messages and drugs were taken.
So I don't want to give the impression that if there was a term valsartan that all consumers would derive the same meaning from it.
Q. Well, I'm not talking about the recipient of the message right now. I'm talking about the entity delivering the message.
I'm saying that -- what I'm asking you is do you agree that by calling it valsartan, the manufacturer that calls it valsartan is intending to convey a message that it's valsartan, whatever that means?
A. Okay.
Q. You don't take any issue with that, right? It's a pretty simple proposition.
A. I don't like answering questions that end in "whatever it means." That's just my comfort level.
Q. Whatever valsartan means. I'm

trying to --
A. I understand.
Q. I heard what you said about that.
A. I understand.
Q. So what I'm trying to do is just focus on a very simple question here.
And is there anything about that that you disagree with, that a manufacturer is not attempting to convey the message that this is valsartan by calling it valsartan, whatever that term valsartan means?
A. Okay.
Q. And similarly with Exhibit 9 we're looking at, this label, prescribing information, there's a message there, or multiple messages in fact, but they all relate to valsartan, correct?
A. Now I will need to read the document. I anticipated this.
Q. You don't think that this document that has to do with valsartan conveys a message about valsartan, or

multiple messages? It's a pretty simple question.
A. I cannot answer that question. I mean, if you're just saying is there communication about valsartan in here? I would say yes. For me, a message has a different meaning, and I would need to read the document to understand what the message -- multiple messages might be.
Q. Okay. Let's go back to your report for a moment, and again that section E that's titled Real-world evidence indicates that the at-issue VCDs held value.
A. Yes.
Q. And I understand you have -- you know, and I'm going to try and short-circuit a long back and forth here by stating that I understand that you have quite a few sources of general applicability here to support what you're saying amounts to real-world evidence of value.
My question very specifically here is, what evidence from this fact situation and case specifically, what

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valsartan-specific evidence do you have that is real-world evidence that indicates that the VCDs at issue had value?

A. I have evidence from the individual depositions from the plaintiffs, and I have quoted some of them, who said that the at-issue VCDs provided them with therapeutic benefit.

I want to qualify, this is a small subset of depositions. I know that there were probably thousands if not tens of thousands consumers who took valsartan and this is a small group. But this is one source of evidence that consumers who took the at-issue valsartan said that -- some of them, not all of them -- that it helped them with controlling their blood pressure, that they had fewer side effects such as light-headedness and dizziness and nausea, and that they did not suffer any extreme emotional consequences to the point of actually seeking professional help. So those are just some examples of value from the real-world evidence.

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I also -- the other sources of value also come from information in the public press as well as in some of the depositions, in the individual plaintiff depositions, where physicians are either publicly recommended, for example, I believe Dr. Neeson, to AARP group members that, you know, they should not stop taking the at-issue VCDs on their own without talking to their physicians because it is more important to control their blood pressure, and they could face very serious consequences, health consequences if they stopped, and that it would be -- the trade-off would be -- even if there were any problems in the short or the long-term with regard to any of the potential cancers, which again would vary across individuals, that the immediate serious health consequence of stopping their at-issue VCDs would be serious.

So the sources, just to sum, are the plaintiff depositions as well as -- as well as physicians. This includes cardiologists who shared that the at-issue

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VCDs held value.

Q. Anything else, or those two?

A. I will also add -- thank you for asking -- the FDA also mentioned that consumers or patients who were taking the at-issue VCDs should not stop taking the VCDs, thereby indicating that they held value, unless, you know, an alternative was available to them. So that is also a source.

So I appreciate your giving me a chance.

Q. Sure.

So you've identified those three things. Is that everything?

A. To the best of my recall.

Q. Sure. Okay. Well, let's, I guess, take them somewhat in order.

You concede, you know, for the first point, which is the plaintiff depositions, you do concede at paragraph 52 that in your view "The statements of consumers, particularly those...in litigation, regarding their retrospective valuation of at-issue VCDs may not be

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reliable measures of even individual value assessments," right?

A. I will say yes and no.

Q. Why are you saying yes and no to something you wrote in your report?

A. Again, because of the context in which you are reading out that one sentence, and I'm going to do the following sentence, which is -- okay, so I read it so I don't have to go through the -- this will be more efficient.

"Nonetheless, testimony of several consumer-plaintiffs in this case corroborates this post-awareness value for the at-issue VCDs," and then we have a quote from Samuel Cisneros. I hope I didn't butcher that.

And "Additionally, many other consumers that even with their current knowledge of the impurities, the VCDs they took were effective in treating their hypertension."

Q. Since you called out Mr. Cisneros particularly, I'm going to mark

Exhibit 10 here.

(Whereupon, Keller Exhibit Number 10 was marked for identification.)

BY MR. DAVIS:

Q. Did you read the entirety of Mr. Cisneros' deposition?

A. I did.

Q. Did you read the entirety of every class rep deposition that you cite in your materials considered?

A. I read some of them, and I reviewed the rest.

Q. How did you make a decision about which ones to read in their entirety and which ones to read portions of?

A. I used a couple of different selection criteria. I was -- in alignment with my MICI framework, I was looking for different types of individuals, you know, male, female, race, education, just to get some variety or variance in those individual characteristics.

I also, for contextual

variance, I looked at things like whether they were smokers or drank alcohol or consumed red meat, so just to give you an example of my methodology.

So I selected as -- like a researcher, I tried to select different types of consumers in the set of depositions.

Q. Were you provided the full transcripts, or were you provided some full transcripts and some incomplete transcripts?

A. I was provided the full transcripts.

Q. Okay. And I get -- I hear what you're saying, that you tried to review some of them based on varying individual characteristics.

How did you decide which of those to review in full and which of those to review selections of?

A. I -- once I started looking and I started reading it, if I thought it was interesting I read the whole thing.

I will admit that sometimes, you know, if it was shorter I was more

motivated, if it was 173 pages versus 349 pages.

And at other times I felt, you know, I was not getting any new insights or information, so then I would just review the rest of the document.

Q. Okay. I mean, we're talking about thousands upon thousands of pages of testimony here, right?

A. I am aware. I don't want to say -- I'm not going to multiply or give you a number, but I know that there were over 40 depositions, and the range was typically anywhere from like 150, 160 pages to like 350 or 400-plus pages, so yes.

Q. Okay. So many thousands of pages?

A. Correct.

Q. So would you have reviewed page 99 of Mr. Cisneros' deposition that I have for you there? Do you see where he says on lines 11 through 13, "[redacted]."

Do you see that?

A. Yes, I do.

Q. Does that sound like someone who would pay a dime for contaminated valsartan?

A. [redacted], which I'm going to object to now because I don't believe that that is necessarily the message that he was given, "[redacted]" is not saying that he did not get any value from it. Because I just quoted something in my report that said [redacted].

Q. Right. So let me see if I understand what you're saying.

You're drawing a distinction between therapeutic value and economic value, right?

A. In part correct. I am saying that the value or worth of a drug will vary by consumers who are going to compare the benefits, and that includes therapeutic

benefits just like you describe, and the costs of the drug, and that includes price.

So you have many other variables going on simultaneously on the benefit and the cost side in order to make an assessment of value.

Q. And for you that's therapeutic value in the context that we're talking about right here with Mr. Cisneros?

A. All I'm saying is as a researcher who is looking at this, I would not assume the value is zero or the drug is worth nothing to him because [redacted]

And even though what I just read is -- [redacted] it does not mean that the calculation of what the drug is worth is zero.

Q. Do you have any reason to doubt [redacted]

A. I don't have any context to answer that question.

Q. Then you -- back to your report, you provide a citation, this is paragraph 52, to it looks like about a dozen or so class reps, right?

A. Yes.

Q. Okay. Did you read all of those transcripts in their entirety?

A. I read or reviewed all of them.

Q. Okay. So were you aware, for example, that Eric Erwin in his deposition, who is in your footnote here, that he stated that non-contaminated VCDs wouldn't even hold value for him if they came from a facility that had issues?

A. I don't recall that exact statement, but I'll take your word for it.

And it supports my general premise that different consumers will take into account different message variables, their individual differences will lead them to put weights on different pieces of information, and the context in which that

they are making this decision, that includes not only their physician but their diet and lifestyle, would all have an impact on how they would use either a compensatory or non-compensatory decision.

So I mean just go back to this footnote. Part of what I learned from reading and reviewing these plaintiff depositions was the fact that many of the variables that I've just mentioned, the message, the individual difference, and the context, were all part of the ecosystem or the wholistic inputs into thinking about the drug.

Q. Okay. You also refer to a Mr. Dennis Kaplan's testimony in your footnote there. Did you read at page 145 of his deposition that "they should never have enabled it to be out in the market where I and other people could have taken it"? Did you read that portion of his deposition?

A. Again, I don't recall that exact thing, but I believe you. If you are stating that was in his deposition, I believe

you.

And again, just your last two examples showed how much variance there is in how consumers would respond to this information.

Q. What about page 18 of Mary McLean's deposition where she says, "I wouldn't have taken it knowing that it was contaminated." Do you recall reading that?

A. Again, I do not recall specifically, but it does -- it does not go against my premise that consumers will have a range of reactions to the recall.

Q. Okay. But you're citing these people in particular to say that they acknowledged it had value, but they're all telling you -- or they're all telling under oath that it had no economic value for them, that they wouldn't have purchased it, right?

A. I'm sorry to repeat this again. Value equals benefit minus cost. They're acknowledging there was therapeutic benefit. That means something positive. Even if some of them are acknowledging that there is no

economic value, one cannot assume that the sum or the difference between all of their benefits and costs would equal not only uniform, but would equal zero.

Q. I want you to -- and I hear what you're saying regarding therapeutic benefit, that there's -- your assertion is that there's therapeutic value here and that has to be accounted for, right?

A. My assertion is that there are benefits and costs that need to be assessed in order to make a determination of worth, and therapeutic benefit is one example of benefit.

Q. So let me ask you to -- I'm going to set forth a hypothetical for you, and I want -- I'm going to walk through it step-by-step, and indulge me here, if you don't mind.

I want you to assume that for all of the at-issue VCDs, that they were all adulterated.

Do you follow me there?

A. Okay.

Q. Okay. And as I showed you in the US Code exhibit I showed you, 21 USC 331, I showed you that it's illegal to distribute adulterated drugs, right?

A. That's the document I did not have a chance to review, is that correct? Are you referring to Exhibit 9?

Q. I'm referring to Exhibit 7 here.

A. Oh, I'm so sorry.

Okay. That's also a document that I did not review completely, and you just read the first page.

Q. Well, indulge my hypothetical here, that all the at-issue VCDs here were adulterated, and indulge me also that it was illegal to sell those adulterated drugs, for example, under 21 USC 331 or Exhibit 7.

Do you follow me so far?

A. Mm-hmm.

Q. I want you to also assume that these VCDs are economically worthless at the point of sale regardless of any medical benefit they provide. I want you to assume

that for me. I know you disagree with it, but I want you to assume that with me, right? Okay?

A. Okay.

Q. Assuming those things, would you not agree that the value of these drugs is zero dollars?

A. I disagree.

Q. Okay. How do you disagree with that?

A. As I said, there is a set of benefits. The therapeutic benefits is just one benefit. So saying to me that there is no therapeutic benefit just makes the value of therapeutic benefits in the set of benefits zero, but not the other benefits.

When you say it's unavailable and the price is zero, yes, there is no economic price or cost in the set of costs, but there are many other costs.

So again, the remaining, not the therapeutic value which you asked me to assume is zero, and not the price that you asked me to assume is zero, there are other

variables in this equation that would determine worth.

Q. I think you misheard the third part there. Let me try it again.

So I've got -- I think we're through two points, right, in this hypothetical, which is that all the at-issue VCDs here are adulterated, that the sale of those drugs would have been prohibited under the law, correct?

A. Correct.

Q. Okay. Meaning that there would have been no supply of them in the market, and no ability for consumers to purchase them, right?

A. Okay.

Q. Okay. And then I want you to assume that the value of those drugs from an economic standpoint as applied to -- that every single person was found to have derived zero economic value from these drugs regardless of the medical benefit they may have provided.

Do you follow me?

A. I do follow you, and I disagree. I cannot -- I cannot respond because I disagree with the basic premise.
Q. Okay. So, well, let me show you something then.
Well, follow me through. I know you disagree with the premise.
A. Okay.
Q. But follow me through here.
A. Okay.
Q. And let's just take it as a fact, even if you disagree with that fact, that for every single consumer of these drugs that there was zero economic value for them at the time of sale, that the drugs were economically worthless at the time of sale regardless of any medical benefit to be derived from them. Assume that for me, that that applies to everyone.
Would you not agree that, assuming those things, that the value of the drugs in that case would be zero dollars, granted that you disagree with the premise?
MR. GOLDBERG: Objection to

form. Foundation.
A. I'm going to go back to my formula and say that there will be a range of consumers, and I have this information in my report, actually throughout my report, so I can't even tell you which section of IV this would belong to, but that there would be a range of consumers who would say that the drug had value to me, or has value to me -- even if they cannot get it, that the drug has value to me because I did not have side effects; the drug has value to me because I had peace of mind; the drug had value to me because I could take it in a single pill form.
And I'll go to the cost side, not paying anything, as you said, that I don't -- the drug had value to me because it was familiar and now I have to learn about another drug; the drug has value to me because now I have to go and talk to my physician about another prescription; the drug has value to me because -- okay.
I'll stop there. So you got my

general idea.
BY MR. DAVIS:
Q. Sure. And I'm trying to exclude that from this hypothetical, and I know you disagree with the premise, I know you do, and you've articulated that. But just follow me through with the premise here, which is that it's been determined for every single one of these consumers who you just posited a list of questions they might ask or opinions they may have, just assume for me that it's been determined that the drugs are economically worthless for them regardless of all that stuff.
Do you follow me?
A. Yes.
Q. Okay. And in that situation, combine that with the fact that all the drugs are posited to have been adulterated and therefore illegally sold, couldn't have gotten them, couldn't have paid anything for them, at that point, with all those premises and stuff that you don't agree with, but just follow me through, would you agree with me at

that point, if all those things were true, which I get you don't agree with, that the drugs would have no value at that point, economic value?
A. Whoever made that determination was wrong.
Q. Okay.
MR. DAVIS: I'm going to mark an exhibit here.
MR. GOLDBERG: John, do you want to take a minute break? We've been going another 90 minutes.
MR. DAVIS: I just want to finish this real fast, and then I'm close to be being done, to be honest.
MR. GOLDBERG: Okay. Got it.
MR. DAVIS: I'll probably want to take a quick break just to go through my notes.
MR. GOLDBERG: Sure. Got it.
MR. DAVIS: I'm going to mark Exhibit 11.
(Whereupon, Keller Exhibit Number 11 was marked for

identification.)
BY MR. DAVIS:
Q. Just to pick up where we left off, you testified to me that you thought that that person who made that determination would be wrong, correct?
A. Yes.
Q. Okay. Do you understand that the Court is that person that's made that determination in this case?
MR. GOLDBERG: Objection to form. Foundation, mischaracterizes the document.
BY MR. DAVIS:
Q. Why don't you flip to --
MR. GOLDBERG: You're marking this as --
MR. DAVIS: This is Exhibit 11, I believe.
BY MR. DAVIS:
Q. I want you to turn to page 20 of the document. The numbering is very small in the top right corner.
A. And again, I haven't had time

to review this document.
MR. GOLDBERG: Somehow we're going to have to figure out what you want to do here. She hasn't reviewed the document. I know you want to ask her about page 20.
MR. DAVIS: I don't really have much to ask her. I just want to --
MR. GOLDBERG: I think you should explain to her what the document is, and give her a second to at least scan it for a minute or two so she can get familiar with the document.
BY MR. DAVIS:
Q. I will represent to you this is an opinion that the Court has issued in this case, a written opinion. Do you see the case header up there, "In Re: Valsartan"?
A. I see that.
Q. And do you see that on the right in bold there it says, "MTD Opinion 3: Warranty Claims"?
A. Yes.

Q. You then you see "Kugler, United States District Judge"?
A. Yes.
Q. Okay. And in fact, that blue version at the top -- sorry, it's blue in my version, but it printed black and white, but you'll see the case number information, Case 1:19-md-2875, document number 775, filed on to the docket January 22, 2021.
Do you see that?
A. Yes.
Q. Okay. So I'll represent to you that this is an opinion of the Court that's been entered into this case. And I just want to -- I'm not going to ask you any detailed questions about it, but on page 20 --
A. Sorry for clarification. So when you say "an opinion of the Court," is that the same thing as the opinion of the judge?
Q. Yes, yes. The judge's order.
A. Thank you.
Q. And on page 20 the Court says, "This court finds that contaminated drugs are

economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sole VCDs actually achieved the medical purpose of lowering blood pressure. Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for."
Do you see that?
A. Yes.
Q. And your testimony is you disagree with that?
A. I did not testify that I disagreed with this. I testified that I disagreed with your example.
I will now say that I don't know the context in which this determination or this decision was made. I don't know what other facts were provided to the Court or to the judge. I am not a lawyer. And I don't know what was the input for this decision, and how -- what the laws are that helped make

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this determination, but to say that a drug is worthless because it's -- let me read that again, even if it is efficacious that the economic value is zero is wrong.
Q. Okay. But you testified earlier that you've never done an economic damages analysis in litigation, have you?
A. Correct.
Q. And you've never done one period, right?
A. Correct.
Q. Okay. And you're not an economist, right?
A. I have a bachelor's in economics, but I'm not an economist.
Q. All right. Thank you.
MR. DAVIS: Let's take a quick break, five minutes, and I'm pretty close.
MR. GOLDBERG: Okay.
MR. DAVIS: We can go off the record.
THE VIDEOGRAPHER: Off the record at 3:29.

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(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: Back on the record at 3:46.
BY MR. DAVIS:
Q. I've just got ten more minutes of questions maybe and one new document for you.
So just to re-cover one area very briefly, do you remember talking with me about -- we were going back and forth about the fact that there's a message embedded in calling the product valsartan, whatever the consumer made of that message or whatever the term valsartan means, I think we agreed that there was a message embedded in there, right?
A. My recall is that this was in response to the document that you showed me that's Exhibit 9 that I didn't review in total, and that I said I would concede that there is communication in there.
In my expertise on health message processing, I could not make a determination if there was a message in

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there.
Q. But there's a communication, right?
A. There's some material, written material in there.
Q. Okay. And your -- and I don't want to overgeneralize here, but your whole focus is oriented towards the consumer, right? You look at things from a mostly consumer standpoint, and that also includes the physician, I suppose, but your whole focus is sort of consumer-oriented, right?
A. I am an expert on how consumers assess value or worth of products and services they're considering, have consumed, or want to continue consuming. And so yes, from that perspective I'm focused on the consumers' assessment of worthiness.
Q. Okay. Would you agree with me that the communication that -- you know, and I'll adopt your term here, communication -- that the communication of calling the drug valsartan, that was a communication that consumers really had no choice but to rely

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on, right?
A. Incorrect. It is very clear that consumers have a lot of different sources of communication from different people, from -- in different formats, and that who would seek what kind of information in different times, in different formats would depend on the individual. It would need to be an individual inquiry.
Q. That's your opinion?
A. Yes.
Q. Okay. Well, flip to -- back to Exhibit 11, if you don't mind.
A. Sure.
Q. And go to page 14.
A. Just give me a moment because I can't see it. All right.
Q. Do you see in the last -- second to last full paragraph on that page it starts with "The manufacturer's very naming of the drug"?
A. Yes.
Q. It reads, "The manufacturer's very naming of the drug as valsartan or

valsartan-containing amounted to an express warranty on which plaintiffs had no choice but to 'rely' when they were prescribed the drug and bought it as a medication for their high blood pressure."

Do you see that?

A. Yes.

Q. Okay. And do you see that that's part of this Court opinion that I showed you earlier?

A. Yes.

Q. And you disagree with that?

A. I said I did not have an opinion on that because I am not a lawyer and I do not have all the information that was presented to this Court before this determination was made. I cannot agree or disagree with this statement.

MR. DAVIS: Okay. I'm going to mark Exhibit 12.

(Whereupon, Keller Exhibit Number 12 was marked for identification.)

///

BY MR. DAVIS:

Q. Do you recognize this as -- I suppose it's not technically your invoice, but it's Analysis Group's invoice to Mr. Goldberg here.

Do you see that?

A. I do.

Q. Okay. And it includes -- it includes the statement that this is just the ZHP share of that invoice for 16.67 percent of the total.

Do you see that on page 1?

A. I do. But I'll be honest with you, I'm not sure exactly what that 16.6 refers to.

Q. Let me ask it a different way.

Did you prepare this invoice?

A. No, no.

Q. All right.

A. When you say "this," you're talking about the page that you're just referring to, right?

Q. Yes.

A. I don't know what's on the

remaining pages.

Q. Did you actually send this invoice to -- okay, somebody else did that?

A. I did not prepare or send the invoice.

Q. You'll see on page 1 it says that the invoice is "For professional services rendered in connection with the above referenced case for the period ending December 31, 2021," right?

A. Yes.

Q. Okay. And your report was signed on January 12th, correct?

A. Correct.

Q. And you've also done some work on the case since that point, right?

A. Yes.

Q. You're sitting here today, for example. Did you sit for any preparation sessions?

A. Yes.

Q. Okay. About how many would that be?

A. Sessions defined by what unit

of time?

Q. Hours.

A. Hours.

Are you talking about preparation that I did for the depo on my own, or only in some other context?

Q. Sure. Any context.

What I'm trying to get at is what your next invoice might look like.

A. I cannot -- I cannot give you an exact number because I have not calculated it.

Q. Do you think that it's -- for example in this invoice you had billed -- you personally had billed 37 hours. Do you think it's more than that?

A. I don't want to guess. I'd like to go back to my records to check.

Q. Okay. When do you anticipate the next invoice being submitted to the defendants in this case by Analysis Group?

A. Oh, I don't know when Analysis Group would submit it.

Q. Do these invoices get sent out

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monthly or quarterly?
A. I don't know what their procedure is.
Q. Okay. It says your rate here is $1,000 per hour, is that correct?
A. Yes.
Q. Okay. And then there's a number of Analysis Group professionals that are also listed here, correct?
A. Should I turn the page?
Q. Sure, on page 2, yeah.
A. Yes.
Q. Do you recognize all those names?
A. Yes.
Q. How did you select those people to work with on this report?
A. I did not select them to work with me on the report. One of the members of the team, Brian Ellman, got in touch with me and asked me if I would be interested in speaking to some lawyers about this case, and I agreed, and I did so. And the lawyers decided to retain me, and this team came as

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part of that.
Q. So you don't know who -- putting aside Mr. Ellman, all the names below him, you don't know how those individuals were assigned to your team?
A. No.
Q. Okay. Did you independently go and vet any of their credentials?
A. No.
Q. Okay. And do the hour allocations here on page 2 look accurate to you, that you billed 37 hours, and this whole team here billed 326 hours --
A. Well --
Q. -- up to this point?
A. -- I'm assuming it's accurate. It's not something that I ever saw until this document was presented to me.
Q. If you go to the third page, the next page.
A. Yes.
Q. You'll see that this is your line item of your work on the case, right?
A. Yes.

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Q. Did you write those narrative entries there?
A. I did.
Q. And would that be the same for -- to the best of your understanding, maybe you don't have any idea, but for these other individuals at Analysis Group, Ellman, O'Laughlin, below, would they have written their own narrative descriptions?
A. I have no idea.
Q. You have no idea.
You would expect they probably would have, though?
A. I have no idea.
Q. So what did these Analysis Group employees do for you on this case?
A. The short answer is that I use them the way I use research assistants. As you mentioned, I got the case -- not the case, sorry.
I got the request to be an expert witness and write a report late last year, and that is when the students are on break. And just like I use the students as

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research assistants, I did the same with the AG team.
Q. Okay. Did that include them writing any of your report in its draft form?
A. The way it works is I work on the report, I ask them for collaborating or supporting material on -- for my opinions, I ask them to read those materials that I provided and find similar materials to help me make a list of the references that I might want to cite or I might not want to cite.
And I also, you know, ask them as they were going through this if they had any ideas, you know, they're welcome to share them. But at the end of the day it's my report, I care about quality, and I accept or reject, you know, any ideas from anyone.
Q. Okay. And your invoice, your time here is complete, in your opinion, up through December 31st?
A. I mean, I will say that I, as in other cases, I don't put in time that's related to thinking or abstract things that are associated with some of the case

preparation. And, yeah, so I will say it's pretty accurate.

Q. Okay. But more tangible things like actually writing the report, that would something you would bill, right?

A. So reading, writing, revising, editing, checking, searching for literature myself, those would be tangible things.

Q. Why is it in your line items for time that the first time the mention of any draft report appears is on December 16, 2021 where you say you reviewed an already existed draft report?

A. That's not how I interpret "review." For me, as I mentioned earlier, as a reviewer and an aid, I think of review as creating drafts, revising drafts, editing drafts, for me it's all part of a review process.

Q. So what you're saying is you may have miswritten the narrative here and this is when you started writing the report, December 16th?

A. No. From my perspective I'm

not misrepresenting it. That's what review means for me.

So, for example, if you use the page that we're looking at, when I say "Review of Conti Declaration and Protective Order," 12/09, I'm already reviewing and writing the report based on what I'm seeing from Dr. Conti's declaration and thoughts in response to the protective order.

When I say "Review of online Valsartan recall materials," I'm already writing parts of the report because I'm thinking about -- I'm thinking about what will go into forming my opinions in the report that are connected with these materials.

Q. Sure.

Go down to Mr. Ellman's hours on page 4, the next page. He says on December 10th that he had a call with the case team and reviewed an outline.

Do you recall what he is referring to by the "outline" there?

A. I do not.

Q. Okay. Was that something that was provided by counsel?

A. I do not know that.

Q. Okay. You'll see that a number of the other Analysis Group employees do have narrative line items regarding their work drafting the report.

Take a look at Laura O'Laughlin on page 4. For example, on December 8th she says, "Assist in preparing expert report."

Do you see that?

A. Yes.

Q. Same thing on the 9th, same thing on the 10th.

And then if you go down to Kate Schoenbach, I believe -- I hope I pronounced that right, she says she "assisted with drafting," and then something is redacted there for a number of days.

A. Correct.

Q. Okay. Same thing with Mr. Jacob Eby, he says that he -- for example, on December 13th he said he assisted in drafting.

A. Yes.

Q. And that's all prior to December 16th where you first mention reviewing a draft report, right?

A. As I mentioned earlier, for me, I started writing the report, you know, and thinking -- you know, thinking through what I would be looking for during that first call with counsel. And I continued doing it on the 9th, on the 10th, on the 16th, on the 17th, on the dates that you see there.

MR. DAVIS: Okay. All right. I believe that's all the questions I have.

I will make a formal request that when the next invoice is submitted that that be produced to us as soon as possible.

And thank you, Dr. Keller. I appreciate your time today.

THE WITNESS: Thank you very much, I appreciate it.

MR. GOLDBERG: Just give us a two-minute break and we can figure out

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if we have any questions for Dr. Keller.

MR. DAVIS: Sure.

THE VIDEOGRAPHER: Off the record at 4:03.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: Back on the record at 4:07.

MR. GOLDBERG: We have no questions for Dr. Keller at this time. Thank you.

MR. DAVIS: Okay. Thanks.

THE WITNESS: Thank you very much, everyone.

THE VIDEOGRAPHER: Off record at 4:07.

(Whereupon, the deposition was concluded.)

COMMONWEALTH OF MASSACHUSETTS)
SUFFOLK, SS.)

I, MAUREEN O'CONNOR POLLARD, Registered Diplomate Reporter and Notary Public in and for the Commonwealth of Massachusetts, do certify that on the 10th day of March, 2022, at 9:19, the person above-named was duly sworn to testify to the truth of their knowledge, and examined, and such examination reduced to typewriting under my direction, and is a true record of the testimony given by the witness. I further certify that I am neither attorney, related or employed by any of the parties to this action, and that I am not a relative or employee of any attorney employed by the parties hereto, or financially interested in the action.

In witness whereof, I have hereunto set my hand this 14th day of March, 2022.

____
MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC
CSR #149108

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, ___________________________, do Hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____

PUNAM ANAND KELLER, Ph.D. DATE

Subscribed and sworn
To before me this
______ day of _________________, 20____.

My commission expires: ________________

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Notary Public

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